ECRI Institute

2013 Conference on the Use of Evidence in Policy and Practice

ECRI INSTITUTE'S 20TH ANNUAL CONFERENCE ON THE USE OF EVIDENCE IN POLICY AND PRACTICE

Data BIG and small: What Healthcare Decision Makers are Using Now

Summary of the Conference Proceedings

ECRI Institute
The Discipline of Science. The Integrity of Independence.

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CONFERENCE BACKGROUND

As technology continues to advance, our ability to collect data on nearly every aspect of our lives has improved exponentially. While amassing large amounts of data has become easier, the question of how that data can be used is still being determined. The hope is that the vast volume of data, often referred to as “big data,” can be analyzed and mined to help solve major problems in healthcare and in business. Yet most of the discussions about big data focus on what it holds for the future, and not about how big data is influencing decision-makers today. With conversations about big data generally addressing its future uses, many fundamental questions are going unanswered.

ECRI Institute’s 20th annual conference, held in Washington, D.C., November 13-14, 2013, brought together 50 policymakers and practitioners and a knowledgeable, vocal audience of more than 500 to take status of how decision-makers are using big data now. Conference attendees gained a greater understanding of how big data is being utilized today by public and private health systems, major employers, providers, insurers, and consumers. Each conference speaker presented the evidence on how his or her organization is using (or not using) big data and explained what their experiences have been thus far.

WELCOME AND INTRODUCTION TO THE FORMAT AND MAJOR THEMES OF THE CONFERENCE

Jeffrey C. Lerner, Ph.D., President and Chief Executive Officer, ECRI Institute

Murray Ross, Ph.D., Vice President, Kaiser Foundation Health Plan; Director, Kaiser Permanente Institute for Health Policy

Jeff Lerner: Good morning. I know people are still taking their seats, and it's a cold morning, but I'm going to try and keep us on time. So, I'm Jeff Lerner. I'm ECRI Institutes president and chief executive officer, and I'd like to welcome you to this, our 20th annual conference on the Use of Evidence and Policy and Practice. And this year, of course, we're dealing with "Data Big and Small."

You can see from this first slide the organizations that have helped us build the conference today. They haven't just lent their names to this conference; everyone has been intellectually involved. Some have been financially involved, helping to support this free public service, and we're very grateful for that.

There are events after the conference as well, both *Health Affairs* and the *Journal of Ambulatory Care Management* will be inviting submissions for papers on big data, and you can check their websites.

So, this is my formal name so that I can remember it. And very quickly, ECRI Institute is a nonprofit organization that has been operating since the late 1960s – since approximately 1968. And we're dedicated to the areas that you now see popping up on the screen: patient safety, risk and quality management, health care processes, medical devices and procedures, drug therapies.

And you know, we have about 400-420 full-time employees. So, in one sense, we are a large organization, and in one sense a small organization. We're large for what we do, and I think that we have such a dedicated staff, that we've managed to create a world-wide presence. And in fact, there are people from around the world in this audience, and we welcome you.

We have a few designations. We're an evidence-based practice center and designated also as a patient safety organization by HHS. We have very strict conflict-of-interest rules, and that's important. Because we evaluate medical technologies, we have to be very careful about our funding, so we don't do consulting work or accept gifts and grants from the medical device and pharmaceutical industries. But that can be mistaken for an adversarial relationship, which would not at all be true. ECRI people love technology. We just do our job to evaluate it and avoid conflict of interest.

This notice is rather important. A lot of health policy has been made at the conference, and we have public and private speakers, and we encourage them to be very forthcoming. That requires that members of the press also make sure that if you're going to quote people, that you talk with them first, make sure you've got it right. Probably the most amazing statistic, in the 20 years of this conference, is that this rule has never actually been broken, and yet there's no enforcement of it other than people's self-restraint. So, we thank you and hope to continue the record.

We had a lot of help in putting together this committee – this conference. People really value the kinds of presentations you'll hear today. So, they contributed intellectually. So, in addition to the formal co-sponsors, you'll see people on this list who gave us their time, their thinking.

And people did other things. Some people gave us mailing lists, or referred us to other people who are creating publication opportunities. That's the type of additional assistance. People do see this as a communal effort. This is not just ECRI's conference; this is an attempt to bring all of us together to address the status of big data and small data and how they interface.

We have our own people at ECRI who really do make this possible, and we thank them. They're on this slide. For those of you who are eligible, there are CME and CLE and nursing credits, and there's information in your packets about that. And we also have a non-solicitation policy. So, you'll see that, other than ECRI's own material, there are no booths or other commercial aspects to the conference.

We thank our speakers in advance. None of them are receiving honoraria. They are doing what we're all trying to do together today, which is to contribute our thinking, our efforts to really try and puzzle out how we are doing in this critical area of big data. After all, big data's in the news; it's in the news every single day. Sometimes for good reasons; sometimes for very threatening or bad reasons. So, it's really a time to look at it, to take status. And everyone participating in this has agreed to do that. No one's even asked for an honorarium, and that's been true for 20 years.

We also thank you, our audience, because you're giving your time and your thought, and there are microphones here, and long question-and-

answer periods specifically designed so that you feel that you're a participant in this conference, not just somebody listening.

So, here's how the conference lays out. We use a format that's like an edited book every year. So, we try to build the conference so that the chapters all make sense. It also means that we'll go from introductory material to conclusion. So, by the time we get to the last session, don't think of it as the last session, think of it as the conclusion, the bringing together of what's come before.

So, if you look at the 12:00 position there, Session 1 is where we're going to start. Now, big data's been around quite a while, and you have to think of it in its historical context. In the 19th century, people wrote with pens. They dipped them in inkwells, and they wrote pens.

The only equivalent of Twitter in that era was the telegraph, where you had to do it in 140 characters or something like that. But there was no telephone, and the invention of the telephone, approximately 1876, really was a big data invention. And it was a different way of communicating, very fast, very different from those letters, those handwritten letters.

So, this is that famous phrase, Alexander Graham Bell calling his assistant, Watson, and the first words said over the phone, "Come here, I want to see you."

Now, here's another Watson, a different Watson. This is the Watson computer that was developed by IBM and will figure in some of the presentations today. In between these years is an enormous amount of work, between the 1870s and our current 2013. And there were an enormous number of inventions along the way, both in technology – the work of Bell Labs was enormous, developing the transistor, for example – but also the information science that lies behind big data, because it's not just about technology. So, that's that Watson.

Since my introduction has to be brief, and there's a second person coming up, it's my colleague Murray Ross from Kaiser Permanente. So, I thought I'd continue the Watson analogy. Murray?

[Applause]

Murray Ross: Well, thank you, Jeff, for that introduction. I'm Murray Ross; I'm with Kaiser Permanente, and I direct our Institute for Health Policy there. And on behalf of Kaiser and the Institute, I'd like to welcome you to this conference, and I think you're going to find this a very special day-and-a-half with us.

Jeff mentioned that this is the 20th edition of this conference series, and I'm pleased to say that Kaiser Permanente has been involved since the inception as a supporter, a planner, a participant. And this is really a unique series. It has covered every topic in health care that you can think of – whether it's health information technology, or technology assessment, patient safety – and many who haven't, but all of them geared to improving the performance of our system, making it more effective, more efficient, and safer.

Once upon a time, this was held at ECRI Institute's headquarters in suburban Philadelphia, where you could easily get lost amongst all the trees and winding roads. We helped convince Jeff to bring it to Washington a few years ago, and that, I think, has been a real success because we're reaching an audience like you. We're, thanks to organizations like the National Academy of Sciences, able to get much larger venues and reach a bigger live audience.

In view of the wind that I experienced last night, coming in from California, I think maybe Sanibel Island or somewhere, for next November, would be a good choice. Beyond the pleasure of working with Jeff and his team, we're particularly interested in this year's agenda.

Since our inception, about 75 years ago, Kaiser Permanente has been a data-driven organization, and it's really fitting that we're holding this meeting almost exactly to the day of the 100th birthday of Dr. Morris Collen, who's the sort of founding father of medical research at Kaiser Permanente.

And this isn't one of those anniversary birthdays. He's still alive, and he's still coming in to consult at Kaiser three days a week, and to attend his birthday party. So, his work has clearly been affected, at least in one case, in enhancing longevity. So, Kaiser is both a leading producer and a leading consumer of data, large and small.

We draw on our digital medical record for our nine million members. We're building a bio bank that will match that electronic medical record data with behavioral and environmental factors, as well as genetic data for about a half-a-million consenting members. We embrace data, big and small.

In fact, we feel we have a duty. There's a lot of knowledge that's wrapped up in – I heard Tom Getz, who was then the executive editor of *Wired* magazine, refer to it as latent data, or latent information, and it's our data to pull that out and make health care work better for our members in our communities.

We also have a duty, of course, while we're doing that, to respect and protect the privacy and security of the information for our members as we use it.

Today will be fun. You saw the road map for the conference. But why do I say that's fun? Well, Dan Ariely – he's a behavioral economist at Duke University, and some of you may have – may read his blog – back in January, he said that big data is like sex. Well, that's not exactly what he said. He said big data is like team sex: everybody talks about it; nobody really knows how to do it; everyone thinks everyone else is doing it; so, everyone claims they are doing it.

[Laughter and applause]

Murray Ross: So, with that, I'm going to turn it back over to Jeff to get us going. So, thank you very much and welcome.

Jeff Lerner: So, you see who has the better jokes. It's him. Okay, so, I thought I would talk very briefly to you about some of the major themes of the conference. This is Murray calling me back up, continuing our Watson theme.

What we want to do. You can see Session 1, which we're going to start very shortly, is going to be an introduction to the infrastructure of big data.

We're going to talk about some aspects of that infrastructure. We can't cover everything, but we have extraordinary speakers who are going to cover a series of aspects, and I'll introduce that in a few moments.

But let me show you, as we go around this clock face, this circle, we'll go from that to a discussion by three chief executive officers of major health systems. And that's going to be an open discussion moderated by Ralph Muller, from the University of Pennsylvania, that will look at what these chief executives think is going on now, what are they doing, and how are they handling a certain set of issues connected with big data and its relation to smaller data.

From that, we'll be looking at EHRs, and we'll look at actually four systems: three EHRs and one overall system in HIE or health information exchange. Because in many people's views, certainly in the provider community, they think of big data, and they think of – they're EHRs; it makes sense. So, we'll do that.

Then we're going to ask, in Session 4, how can big data make a health system bigger and better, or can it? So, that's an important question, why are we doing this, and what are some of the pitfalls? Then we're going to look at patient safety, clearly a critical issue and one of the major uses of big data.

From there, we're going to talk about the kinds of partnerships, because in big data, usually organizations don't go it alone. And that's very challenging to go across organizations. So, we're going to discuss that. And then, of course, cost and quality. Everybody wants to know about both of those, and that will be a session – these last three sessions are tomorrow.

And then we get to that last session, which is not a rum session. That's what I was saying before; it's a conclusion, because threaded through many of the talks is a question, does big data help us close that gap between individual health and population health? So, the last session's quite key.

So, if you're one of those folks who always feels, "Well, I always leave when it's the last session," that's like leaving before you find out who

done it in a mystery. Okay? So, we urge you to stay with us and see how this concludes.

Okay, well, I'd like to invite up our speakers for the first session. So, Ralph, that's – excuse me, I'm sorry – George, Troy, and Larry. Now, we've asked you to look at the bios of each of the speakers ahead of time, which are on the website, for all of the sessions, so that we can get into the sessions more rapidly.

And because many of the speakers – most of the speakers – actually, all of the speakers have extraordinary bios, and it would take a great deal of time to go through them, but you can judge them in another way, by what they say here today.

So, the format for this session is going to be first individual presentations, followed by a discussion among the panelists, and then we're going to open it up for 20 minutes for a discussion with you.

And in the – the first person who's going to talk is George Bo-Linn, and George will provide an introduction and his views on big data. And George, let me ask you, are you going to tell them who Gordon Moore was?

George Bo-Linn: Yes.

Jeff Lerner: Okay. Then I'm not going to say anything more than that. I'll just introduce you to George Bo-Linn.

SESSION 1: CREATING INFRASTRUCTURE FOR BIG DATA IN THE PUBLIC AND PRIVATE SECTORS

The "infrastructure" for big data is comprised of far more than the information technology necessary to gather and analyze it. Innovative projects and programs are underway. This includes new capabilities to develop the medical research infrastructure that is changing approaches to individualized diagnostic and treatment options for physicians and patients in areas such as breast and other cancers. In addition, the information systems and changes in operations of businesses, like retail pharmacies, can and do inform healthcare more broadly. This session is designed to help us define and understand important aspects of the current big data information infrastructure … warts and all.

Moderator: **Jeffrey C. Lerner, Ph.D.,** President and Chief Executive Officer, ECRI Institute

George Bo-Linn, M.D., Chief Program Officer, Patient Care Program, Gordon and Betty Moore Foundation

Troyen A. Brennan, M.D., M.P.H., J.D., Executive Vice President and Chief Medical Officer, CVS Caremark Corporation

Larry Norton, M.D., Deputy Physician-in-Chief for Breast Cancer Programs; Medical Director, Evelyn H. Lauder Breast Center; Norna S. Sarofim Chair in Clinical Oncology, Memorial Sloan-Kettering Cancer Center

George Bo-Linn: Thank you, it's a privilege to speak and to engage in a conversation with you during the panel discussion. As Jeff mentioned, I'll be doing a high-level overview, and as is the theme of this particular section is infrastructure, I'm going to be talking about the new infrastructure for our minds. I won't be talking about big data, because you'll hear about that. I won't be giving you case studies, because you'll hear about that.

What I'm going to try to do is to highlight, at least from the perspective that I have, and that we have at the Gordon and Betty Moore Foundation, as what does the value of big data mean, and how do we achieve that by developing this new infrastructure for our minds? So, it'll be what, why, how, and then so what; as it would be for team sex, so what?

So, what is big data? You'll hear about this more, but I think the more traditional explanation is that presented by Doug Laney, in 2001, before he joined Gartner. And it's the three *V*s. You have data complexity, which is larger than that which could be managed by traditional analytical tools because of the *volume* of the data, the *variety* of the data, variety across different data sources, and, of course, the *velocity*. In other words, how quickly that data comes in.

The volume, variety, and velocity is pretty well known. We experience it all the time, where they were on their smart phones, or where they were things on the Internet, shopping Amazon.com. There are two additional *V*s I want to add, and that is *veracity*. How do we understand truth in this big data, which I think is incredibly important relative to the analytical components, and as I mentioned, the infrastructure of the mind. How do we understand the implications of big data? And even more importantly than that fourth *V*, I will add a fifth, and that is the *value*. Because if we don't understand the value that translates into action that results in improvements, there is simply the "what" and no "why." And I think the why is incredibly important.

Why are we facing big data at levels unprecedented from when Alexander Graham Bell spoke to Watson? Those are – include Moore's Law. Gordon Moore co-founded Intel Corporation in 1995. He wrote a seminal article about the number of transistors on a semiconductor will double every two years, and that Moore's Law has driven Silicon Valley, has driven the opportunity we have to understand big data. And Dr. Moore is now devoted to philanthropy, and I'm pleased to be part of the Gordon and Betty Moore Foundation.

Gordon, who is an extraordinarily modest man, understands the power of not just Moore's Law as an observation, but rather Moore's Law as driving reality, because no one wants to see Moore's Law fail. In fact, one time I was at a dinner with Gordon, and someone asked him what would happen if the president of Intel were to be in place during the time that Moore's Law finally fell? And he said, "That would be the grounds for early retirement." So, that kind of drive in Silicon Valley creates our opportunity to understand big data.

Why is big data so big? This could very well be a photograph of the records office in my private practice. I was in private practice for almost 15 years. Now we have the ability to put this into a thumb drive. I won't go through the variety of data compression, data generation, and data dismay that we're facing now. But the opportunity we have in health care, for the first time, is the digitalization of our practices, of how we take care of patients, when we take care of patients, and even more so, what patients are doing for themselves.

This opportunity for big data being so big then addresses "how." The how of big data. How it's visualized. The enormous complexity, size, velocity, and variety of data is unimaginable to the usual infrastructure of our minds. It is incomprehensible. It is beyond dismaying. This, for example, is a chronograph of the activity on Wikipedia that highlights the activities in a way that perhaps we can just begin to understand some pattern, pattern recognition.

How it's visualized can be put into various means. In fact, there's a whole cottage industry on data visualization. How we, however, see it, as info-whelm, where we are so burdened by the amount of data – just raw data – not even talking about information, that we find ourselves suspended by the burden of all of this data. So, how we see it is incredibly important. Chronographs are useful, but it doesn't help us understand the value and the application of big data, and that's requiring tools that are embedded in human's factors engineering and cognitive function.

Simply presenting big data in a way that doesn't allow us to understand how to apply it is a technical exercise in seduction, but it doesn't help us. The promise, as highlighted by the McKinsey Global Institute, is that the sector could create more than $300 billion in value every year. Two-thirds of that would be in the form of reducing U.S. health care expenditure by about eight percent. I would, however, point out the big data promise in this particular assertion begins with the idea that if U.S. health care were to use big data creatively and effectively to drive efficient equality, if U.S. health care were to use big data creatively and effectively would be the same thing as if pigs could fly.

Let's be real here. Big data currently is about 5K of useful information and petabytes of useless information. Big data, then, by the poet, is seen as, "Where's the wisdom we have lost in knowledge? Where is the knowledge we have lost in information?" And I will add to that, if I could be so bold, "Where is the information we have lost in big data?" Not simply the data that we discard on a routine basis, because we don't have enough information, knowledge, wisdom to be able to capture that data for use. Re-use data is a key part of other industries.

The reason that we have predictive text on our smart phones is because an industry decided that the data discarded from misspelling actually had value. It could be that the data discarded

by our patients, because we don't have the wisdom to capture it, is lost. And yet that, in fact, could be the biggest source of knowledge, value, and veracity.

Necessity. Big data in 2013 plus will be that we need data hygienists to clean it – perhaps before that, we need data janitors just to find it – data hygienists to clean it, data explorers to mine the data, business solutions to find value in it, and campaign experts to get value from it. Because if you clean it, you mine it, and you find value in it, but our infrastructure of the minds and the organization of our organizations are just simply not able to address the knowledge that we find, then there is no value. To say that we have algorithms, but have no way to address them in the organizations and processes that we manage, is simply, again, the seduction of big data without meaning.

So, we've gone through "what" is big data in the more technical explanation; "why are we now faced with the challenge and opportunity of big data'; "how" do we think about/use big data, particularly in terms of our meager human capacity to understand the volumes of data that are now available. So what? Today and tomorrow will be about that "so what." But let me give you some high level viewpoints, at least, from the perspective that I have gained.

So what? So what is big data? You probably recognize this as the Gartner Hype Curve in terms of expectations and productivity plateau. We have speech recognition. I think many of us remember when speech recognition was simply an idea, and now speech recognition is quite common. In fact, one never talks to a person anymore. It's always a computer who speaks to you. I don't know if any of you tried to change your airline reservations through the phone, two archaic concepts, I know, but you never speak to a live person. So, speech recognition has reached the level of productivity.

If we talk about innovation, innovation would be like 3-D bioprinting. In other words, that we can actually print out tissue that we could use as a ligament repair in a torn meniscus.

Virtual reality. I think that's the trough of disillusionment. How many times have we heard, "Virtual reality will free us to create simulations that enhance our lives and increase our productivity"? I would say that that is in the trough of disillusionment. And if it does exist, it only exists right now in the gaming industry. If you took a look at the slop of enlightenment that would be, for example, Wii, the device that reads gesture control, or the new Apple iPhone that is being able to interpret gestures.

So, in the terms of the expectation, "So, where is big data," Gartner currently thinks that big data is at the peak of inflated expectations. Your job, today and tomorrow, is to assess that assertion and to decide whether, in fact, big data, as applied to health care to find value, is simply hype, or it will take us to the productivity plateau, where we fervently hope it evolves.

Big data as Big Brother. Currently, the Gordon and Betty Moore Foundation has invested several millions of dollars in various centers throughout the country to try to evaluate whether we can create algorithms for predictive analytics, whether those be readmissions to the intensive care unit, readmissions to the hospital, or various other predictors of clinical activities or consequences. Those would be two. For example, in Dallas, Ruben Amarasingham, at the Parkland Center for Clinical Innovation. We also work with Gabriel Escobar at Kaiser and other centers throughout the United States, trying to understand how we can apply big data applications through algorithms of predictive analytics that were honed by big data, through machine learning, to make those algorithms even more accurate.

As you know, we search for big data because we use it to hone our instruments. The instruments that we use, then, could be seen as facilitating Big Brother. Big Brother being, as you know, one in which no thought, action, behavior, activity, consequence is hidden. It's all captured. The ability of Hadoop and Accumulo – new tools that are available now – Microsoft Azure allows you, in fact, not to even think about what data you can ingest, because with cloud-based services, Amazon Web services being the premiere at this time, there are no more constraints.

So, when I was in practice, the constraint was, "How many charts can you put in a room?" Those constraints no longer exist. There is infinite capacity for data ingestion. Therefore, what do we in health care believe should be in place as safeguards against Big Brother, much less against – dare I say it, but they're monitoring me anyway – NSA – whom I hold in the highest regard, by the way.

We move from, then, big data as Big Brother to big data as the matrix. In fact, if big data allows us to develop tools that are so accurate through machine learning, perhaps we no longer exist as humans. We, in fact, can be so predicted that we are simply images on a screen. It could be, as you've seen and I've seen so often, in visiting hospitals and ICUs in particular, big data is now computer rounds, where the need to see the patient, talk to the patient, examine the patient is no longer necessary because we've captured it on our screens.

How have we been, in fact, changed by big data? How have we, in fact, changed our understanding of who we are and the confidence in ourselves because now we have the ability to know exactly where we are through GPS or through smart phones? Such as AirStrip will tell you all these wave forms on your smart phone, so that we may move to big data as master, wherein you know where you are through the GPS, where you need to go, because you then follow the GPS. My wife and my car wife have fights all the time – as to, "Where am I?" As a typical male, I don't listen to either one of 'em.

But what happens then, if we, as physicians and nurses and other health care providers, then, are told by these fabulous algorithms, honed by machine learning of these enormous datasets, to order this test, that our intuition and clinical judgment becomes an impediment to the speed of providing the most effective care? What does it mean if big data can be a disruptor?

To think about it, is big data just a whole lot more data, or is it beyond only hypothesis-driven experimentation to include correlations-driven realities, new modes of research? What if it means that big data as a disruptor is it's dangerous unless it's built on trust? And we may, in fact, develop new social contracts with our patients, so that patients themselves may become, for example, data donors.

Perhaps even more important than being organ donors is to be a data donor. What does it mean, as a disruptor of illusions of big data, unless filtered by big judgment? The infrastructure of our minds reconfigure to understand new aspects of leadership and contextual insights.

So, we are at the event horizon of the black hole. The black hole, as you know, will suck us in without a trace. And the event horizon is at that point where we are so attracted by the big hole that we fall into it and are lost, or we know where to stay so we can both observe the phenomenon and still preserve ourselves as individuals and as those who provide care. At the event horizon of the black hole of big data, where will big data take us? Thank you.

Troyen A. Brennan: So, I'm going to talk a little bit about sort of how you see big data from the point of view of a for-profit concern. I think that's what I was supposed to do today, and I'll just use some brief examples of how we're kind of looking at it. This is a slide about who we are, CVS Caremark.

I only put that up because we do have a lot of data coming through. We've got about 70 million people in our pharmacy benefit management company, Caremark, and then while we deliver about a billion prescriptions a year through the CVS retail pharmacies, and we have about 2 million people a day coming into the 7,500 pharmacies, and we're developing the retail clinical functionality, our electronic medical record contractor tells that we'll be the second largest to Kaiser in terms of number of ambulatory visits in two years. So, that's a lot of data that comes through, and we do tend to capture data well.

The pharmacies were wired up or electrified long before the rest of health care, and we can use that data in a fairly supple fashion. So, we do have access to big data, and there's a lot of big data companies out there right now that some of them come in and sort of visit with us, and they've got a lot of interesting ideas about sort of how to manipulate the data with simulations and optimization and enumeration.

I saw a presentation from a big data company recently about analysis that was done on a PBM – now defunct PBM – merged with another one of the PBMs on drug interactions, and they demonstrated how they went through over 45 quadrillion hypotheses, and they eventually identified a relationship between Plavix and Omeprazole, which got a lot of press. The idea was that if you were on both Plavix and Omeprazole, you were at higher risk for having a poor cardiac outcome than you would be if you were not on the Plavix. But the question is, is that interaction really for real?

And I come at this from the point of view of having been a medical student at Yale and working with Alvan Feinstein. I was never a fellow under Alvan Feinstein, but Feinstein was the original sort of clinical epidemiologist and terrorized a whole generation of people who were trying to do clinical epidemiology in health care centers at the national meetings.

But his big concern was that you shouldn't examine data without a very strong hypothesis, and that the data should be put together in order to examine the hypothesis. And that's not what big data does. Big data's like big slicing and dicing, and people think just because you've got a bunch of data, you should be able to run it through these machines, with a series of simulations, and knowledge is going to come out. And Alvan was very worried about that, and maybe appropriately so, because when you look at the Plavix story, Plavix/Omeprazol story, what was done was finally it more or less randomized control trial.

It was published in *The New England Journal* in 2010 by Bhatt and colleagues. And what this shows is basically the sort of Kaplan-Meier plots about what's going on, both with regard to developing GI symptoms – if people were on Omeprazol, they didn't develop as many GI symptoms. And yet there was really no difference that they could demonstrate between cardiovascular events and cardiovascular outcomes for people who were on placebos as opposed to people who were on Omeprazol.

And the final analysis was there's no interaction, really, between Omeprazol and Plavix. Now, this is still a big data company out there today, talking about the interaction, but the interaction's been relatively well disproved. You can see these P values here; it's a specific study that was done for the specific purposes of examining the interaction.

So, that's why I start the talk by saying, "You've got to have a certain amount of skepticism." Just because we've got literally billions of data points coming through daily for our enterprise doesn't mean that there's anything smart for us there. So, I think that you have to take big data with a grain of salt. And obviously, some of the things that George was saying resonate with that, and this notion of sort of correlation and causation, which is, of course, key to long-term clinical epidemiology, I think is going to become ever more important as people do examine the sort of strengths and witnesses of what would be considered sort of relatively hypothesis interrogation of large datasets.

Now, having said that, we have been using what might be considered sort of big data firms to do some analytics for us. When I first got to CVS, we were trying to decide what were the best stores to put our retail clinics in, and each of the retail pharmacies has about a thousand different data points that they identify, that range from the number of cars going by every day, to the people who are shopping the store, to the things that are sold within the store, the prescriptions that are being rendered there.

And so, we thought we could sort of take that data and analyze it with the existing retail claims we have and identify what are the best stores to put retail clinics in. Really important issue for us, because these retail clinics were losing a lot of money, and it seemed like it was random in terms of which were going to be busy, and which weren't going to be busy. So, my analyses ended up showing nothing; I couldn't find any substantial factors.

So, having given up on that, and somebody willing to do a sort of pilot for us for a relatively limited amount of money, we engaged a firm. And they did do some very much more interesting computational methods, based in mathematics than what we were able to sort of pull out of the bag, being kinda epidemiologically oriented.

And what they've come up with is a much better set of parameters. So, now we've got all 7,800 of our stores basically rated from 0 to 7,800 in terms of which ones would be good for putting a retail clinic in. And what we've found, over the course of the last three years, as we've expanded the number of retail clinics, is that we're really hitting the mark; they're getting a great R-squared.

These show basically the sort of current MinuteClinics. That is what MCs are on the left-hand side, and then our more recently opened Minute Clinics. And what we're finding is higher and higher correlation. So, they're getting R-squares up in the point 6.65 area, which for us is great. So, this has been a really important business outcome for us, using what might be considered big data, because they're running literally, well, I'd say billions of data points through these analyses in order to come up with the algorithms that we use. So, that's really successful, and now we're sort of orienting ourselves a little bit more towards health.

This is a rendition of a graph that appeared in a paper that we published in *Health Affairs* about a year ago, and what we were trying to do is demonstrate the certain interventions that we were doing were improving patient adherence. I'll only use it to sort of make the point about adherence. These bars are basically percentages on a – Y-axis is percentage of people who are taking their medication, and then the bars go out for 18 months. Each bar is a month, and what you can see is the blue people are people who, at six months, we intervened on and put a program in place to try to improve their adherence. And we demonstrated that it was successful, and then we turned it off.

The intervention is not that important. The important thing here is, first of all, people don't take their medications. This is well documented, that over a period of eight to ten months, people on chronic medications stop taking them, and that's a big issue for us. It's a big issue for us in terms of being a health care company. Because if they can get adherent, their costs will be lower, their care will be better, they'll suffer fewer poor outcomes. And also, from a business point of view, if they're adherent, they take their medications, and, obviously, that's our business interest. So, addressing adherence is really important.

The other thing that's important is, as this shows, if you turn off interventions, then people stop being adherent. And so, that means we've got to be very careful about sort of trying to find out who are the people who are going to be adherent, and who are the people who are not going to be adherent, because we want to spend all of our time on those people who are not going to be adherent.

The last point that this shows is that this is just the summary. And so, what we're doing with big data now is trying to take this entire group and have them not just sort of showing on one graph, but what's happening to different subgroups within this, because we think there's different patterns. You can use big data to fit people to sort of different sets of behaviors, and as a result, different curves in terms of what they're doing with regard to adherence.

So, we have a Pharmacy Care Research Institute that we have about 70 or 80 people in, and we work very closely with research teams at the University of Pennsylvania and at Harvard University at the Harvard Medical School. And our Harvard Medical School colleagues put this together. They've identified certain phenotypes of people. So, certain characteristics of people cause you to fall into a certain phenotype, and those phenotypes have different patterns.

You can see, if you look at Number 5 down there, that's a group of people who very quickly sort of fall off, whereas group Number One is a group of people who are staying adherent all the time. So, what we're doing with these datasets is basically trying to figure out what are the predictive analytics associated with who's in each phenotype, and then we'll concentrate our activities on 4 and 5.

Now, the interesting thing about this is if you take these phenotypes, then look at their outcomes, what it shows is that the people who are not adherent – so, like the orange – the large sort of burnt orange group is Group 5, those are the people who are not adherent. And you can see they suffer many more poor outcomes in terms of heart failure, acute cardiovascular events. And so, this demonstrates that this phenotype really does work in terms of identifying people not only who are not adherent, but then who are going to have poor outcomes as a result of that. So, that's something that we're really excited about.

The other thing we're doing is trying to layer on a variety of different sort of analytic techniques. So, take logistic regression, then put census variables in, putting clinician-selected predictors about what's going to happen, you've boosted regression. And then take all of that and take the information for the first three months of what happened to that individual and repeat that process. And what we're finding, as we sort of layer these things on, is that we're getting a really high R-square, especially when we take sort of what's happened in the first three months somebody's on a medication.

So, these R-squares in the .83 to .85 area are really sort of off the charts, unprecedented high. So, this is something that makes us think we're getting closer and closer to be able to sort of predict, with reasonable data that's available just through the PBM data that we have, who is going to be taking their medications. That'll be revolutionary for us. It does suggest how big data can help in health care, because these people, if we can get them to be adherent, will have fewer poor outcomes, will reduce the amount of suffering these individuals have, will reduce costs overall for the health care system. So, that's exciting.

Now, the other things that we're doing, and this goes to sort of extension of big data, these are basically sort of regular logistic and boosted logistic regressions that we've done, and again, we're looking at an R-squared here. What's our ability to predict whether somebody's going to have a PDC at the bottom as a prescription is basically demonstrating whether or not they've had their medication. So, it's a medication possession ratio of greater than 80 percent. How able are we able to predict them?

Well, you can see if we use regular regression, then we boost it, which is a sort of big data technique, we can get a much higher R-square. Now, on the right-hand side, we're taking not only the claims data, but we're also taking some data from front of store. It's all washed; this is all double blinded. So, we can't tell who these individuals are in these kinds of analyses. But all you can see is that some of that data from the front store boosts what we are able to do in terms of prediction. So, I think that's a second plank of big data, taking datasets that are normally disparate, bringing them together and trying to understand whether or not they can help in terms of increasing the accuracy of what you're doing.

So, I would say, from our point of view, we're excited about the ability to do sort of better analytics. The term *big data* itself fairly meaningless to us. We think you have to be very careful in terms of just going out and trying to sort of run regression after regression after regression and try to find some needle in the haystack. We don't think that's a good way to go. Slicing and dicing is not it. But if you're careful, and you're more or less driven by carefully developed hypotheses, and then you build analytic on analytic on analytic, we think that there's going to be some real promise out there.

And from a point of view from a company like ours – we see ourselves as a health care company – improvements overall in health care, but also, from a big company like ours, improvements in the way in which our business operates. Shall I leave it there? Thank you.

Larry Norton: So I'm Larry Norton. How do I make this go forward. Is it this button? Okay I'm a Memorial Sloan-Kettering Cancer center and before I start to talk about big data I wanted to tell you about my experiences with adolescent sex. I found myself in high school be the person that all my friends came to ask me questions and I realized that I was very good at getting confident answers when I had no idea what I was talking about. So I knew that my true calling in life was to become a physician. And here I am. But I am trying very hard to use this big data revolution or big data evolution or big data change. And here I am but I'm trying very hard to use this big data revolution or big data evolution or big data change to make myself a better physician or to make my colleagues better physicians. And I think that this is probably a point in history that fits the paradigm where all major advances happen in terms of science and technology which is a confluence of understanding a question in detail and the evolution of technology with the potential for answering that question And I really do think that we're there. And I just want to describe to you very briefly so we have maximum time for discussion, two projects that I'm involved with that I think are approaching this issue in a creative and we hope productive way.

First of all if you look at a medicine and I'm a cancer physician so most of this is oriented toward cancer medicine and this the first part of my few minutes is concerned with American Site of Clinical Oncology and a project that we're involved in. If you look at the number of patients treated with a new medication the line down the middle where it says license means marketing, means in getting out to the public. There's an increasing number of trials that are particular randomized clinical trials to establish the validity of the drug, we call them phase one, phase two and phase three and at the end of a phase three trial demonstrating safety and efficacy to a degree sufficient to the FDA to approve it as a medication it gets licensed and then all hell breaks loose. The number of randomized clinical trials which is in brown, drops very, very dramatically down. There are observational studies and registries some mandated by food and drug administration and some are occurring because of scientific interest but they're just observational studies. And then the big blue curve is the experience in the clinic with the actual treatment of patients. It peaks and then it goes down as new drugs are introduced. But you can see that the vast amount of information about a new medication in cancer is totally lost to us and we don't have any idea what's really happening because we don't have the connections between those various data sets.

A very good example is Viox. Not a cancer example specifically but I think a very good example that illustrates this from the time of FDA approval to its withdrawal due to a significant increase in myocardial events with 61 months. If we had Kaiser type data to analyze in this regard with 7 or 8 million patients follow and seen the outcomes it would have been cut in half to 30 months and if half the country were being tracked it would have been cut to six months and if we had

the data on all the patients using Viox in a matter of weeks we would have seen the signal. And yet it took us so much longer to see the signal because the fact its catch us catch can anecdotes then retrospect looks at observational data and so on. And this is a huge problem that we face a physicians because again we're giving advice with great confidence when we don't know what we're talking about because we don't have the universe of experience to rely upon when we're making those recommendations.

Now the fact is and I know we're going to talk about this in the next session, that's the problem point in terms of the confluence that I'm talking about. The answer is the fact is we are gathering that information and that is when we're talking about electronic records. Health and medical records and indeed in oncology in our community, the American Site of Coto oncology survey's we are finding out that 60 percent of practices have sophisticated medical, digital records right now. Another very high parentage have basic 16 percent or so have basic tools in this regard and pretty much everybody is looking forward to digitalize their information. The problem is that's it's staying there and a little bit is shared obviously with insurers and insurers really use that information in a very real way or they think they're using the information in a productive way but for the most part the information is out there. And it's in a form that is accessible it's just that we're not bringing it in to a place where we can really look at it and really analyze it appropriately.

So the problem to be solved is the fact that this is what's going on with health care now even to this day for the most part. The providers, let's say physicians nurses. They seek out content from various sources. We'll talk a little bit more about that in a second. They enter the data into some form, electronic medical records. Sometimes hand written notes. Sometimes dictated notes. The care is fragmented because it varies enormously from place to place and from doctor to doctor and also key information may be missing simply because in this system not everybody knows what the key piece of information are. It's like the example you saw from Care Mark. You look at certain set of data you think you're looking at something, you need other data to be able to make decisions that you're not accessing because you don't know that you need it. And actually finding out what works in the real world requires years if we can find it out at all. We're not getting the 97 percent of information that's out there in some way that we can look at it.

So the ASCO Cancer Link Project is trying to deal with this in this way. At the point of care data is taken in, now more and more that data does not have to pass through human hands to be taken in. You put a blood pressure cuff on somebody and that data can go right into the computer as well as showing up on a screen to the physician. Same thing with laboratory tests that are blood based or urine based is that the processing of the information can actually go into the medical record at the same time as it's going into the eyes and the brain of the physician. It has to be transformed in a way that it can be utilized and aggregated and analyzed and then go through a process, that's the little circle on the lower left where stuff is done to it to try to understand what it all means. And then on the basis of the stuff that's done it goes back to the clinician in a form of services. And so that the content comes to providers at the point of care. It is in a useable form right away without multiple injuries and there is an interaction between the

system and the actual care. And this will allow for the stuff I mentioned to happen. Which is learning from every patient so that we can then proceed and really gather information from a real live basis. So we have about 170,000 records already in Cancer care that's being processed in this particular way and obviously the improvements happen in an exponential fashion in terms of our ability to utilize it because of the 15 minutes I can't go into that detail.

But I would like to talk about another project that we think is going to be very relevant to this and these are two linked projects and this is one of the services to be provided is what we call Decision Support. Very important two terms. The decision, something has to be done to help the patient. You make the prescription, you do an operation, you order a test but the concept of support is that the machine is not making the decision. The decision is still made by a human and I think that is something extremely important that we have to discuss. It isn't, you think of the example on the automobile of a map saying turn here. What if that just turned your car rather than letting you make the choice whether you want to turn here. That's the biggest danger that we have to avoid as we start to institute these systems. And I hope we'll talk a lot about that as we proceed forward.

So at Memorial Stone Academy we have a partnership with IBM and using their Watson computer. Which everybody in the room knows is the best jeopardy player ever in history because it had the world knowledge when it went into it. That's an old version of Watson much improved since then. But can actually use language. What's happening now is lots and lots of data, some of it being information, some of it being knowledge is processed through a human being who interacts with the data, who interacts with the patients and comes out with the right treatment for the patient. This is still just the traditional system. In oncology. Contemporary is changed because of the massive amount of new information that the physician has to process. And this is particularly, that symbol there is an expression profile actually of breast cancer showing that the genes that are turned on in breast cancer really determine to a very large extent the behavior of the tumor in terms of natural history, in terms of response to therapy, in terms of impact on the patient's life. An astonishing amount of information is so produced and that is now coming rapidly into oncology practice at a time when the physician trained in the traditional ways does not know really how to use that information because frankly nobody really knows how to use that information. Again people are talking as if they know how to use it but nobody really knows how to use it because those clinical trials are just really in progress at the present time.

Just to give an illustration of what I'm talking about this is the latest publication, this actually a pre-print from something called the Tumor Gene Atlas Project. Certain subtypes of breast cancer are in the various colors on the left. Those are all common somatic mutations that may occur in various tumors. Clinical data is there and integrated with this. Copy number status is not just mutational status but how many copies of genes are present or how many genes are actually lost. And this is an astonishing amount of information that we're just beginning to learn how to process and collect in networks and trying to correlate with clinical outcomes and correlate it with clinical decisions and show that those clinical decisions are associated and perhaps causative of good or bad outcomes so we can learn from this. This itself is a huge

topic in big data circles and I'm sure some of you are working on this as well. How to make sense of the extraordinary amount of information that we're gathering from the analysis of tumors. So pity the poor clinician who gets a printout you know, "You're patient has these 80 mutations and has these copy number variations up and these losses, go." And this is a revolution in biology and is directly impacting patient care now.

So the objective of the Watson Project is trying to make sense of this and to increase the cancer doctors ability to apply guidelines which are not necessarily rules of behavior and that's something that I just want to emphasis and I hope we get back to it. For the very younger generation, not old folkies such as myself, guidelines for the most part have become rules of behavior and this I think is one of the biggest dangers that we're going to have to face as we go under this massive change. Taking the physician really out of the decision making process because making the physician part of the machine in terms of how the information is processed. The machine says do this and we'll show you how we're trying to deal with this. How successful I don't know it's a process of evolution. Current evidence is worldwide evidence. The machine can read English, everything is published in English in oncology is going into the machine because obviously it can read it at the speed of light and can process the information so that if a rare mutation is associated with something in an obscure journal somewhere else in the world as long as it's published in English it's going into the information center, the brain of the machine and take all that and turn it into patient specific treatment and recommendations. It's aggregation and synthesizing patient information, it's taking that and turning it into potential actions and it's basing recommendations. And the key word is confidence in those recommendations based on the expertise that already exists in the doctors taking care of patients at Memorial Sloan Cancer Center.

What really started our enthusiasm about doing this is that when we looked at the practices of experienced physicians they were remarkably consistent in their recommendations despite the fact that there was tremendous variety in the data input that they were receiving. Not coming out with the same treatment for everybody but coming out with appropriate treatment that was consistent with appropriate data points. How to capture that wisdom in a machine is what we're trying to zero in on. So this is where we think the decision support link to the cancer link is going to happen. All that information including the molecular information is going to go into this Watson machine. The patient and the physician are involved in interactions with this process. I can't go into the details again because I'm on yellow light already, and interactions with this process. And there's going to be a process currently in place using natural language processing, using machine learning and having the machine come out with predictions in terms of the optimal therapy of the patient that is then vetted by experts in an interim process so that we can derive optimal outcomes for the patient. And I hope we'll discuss more of this as we go forward.

This is an information synthesis phase which is relatively easy, gathering all the information and putting it in some fashion that it all makes sense and then the important part of this in terms of treatment and recommendations is there are recommendations and levels of confidence that are associated with those recommendations. And it very well might be that a recommendation

is made for which there is not great confidence and that's very important for the physician to know. So my joke about adolescent sex is not entirely a joke. It's that very often you have to make decisions and the way great clinicians do it is they often will do the least toxic thing and see what happens. And there's an interaction between the therapy decision, observations for the therapy decision and then subsequent decisions going forward. And collecting data in real time, processing it in real time and having that interactive phase is going to be a very important part of what we're trying to achieve.

Our goal is obviously is a tool outcome but also as a tool for research and a tool for training. Right now I can take a good internal medicine graduate and turn them into a good oncologist in about two years of training. And I use natural language to do it. And case interactions. And to do it. If it can be done with a human with a capacity of humans to process data we think it can be done with machines as well as we proceed forward. We'll integrate and synthesis guidelines and their not firm rules, those levels of confidence about all decisions, the worldwide evidence that nobody no matter how expert they are knows everything that's happening in the world but the machine can. And be able to support oncologists not only at Memorial Sloan-Kettering but everywhere throughout the world by access to this machine and to do research continuously to try to improve the process. Thank you all very much.

Q&A:

Jeffrey Lerner: Well, I'd like to thank the three of you. And now we're going to move into our virtual living room. I hope you'll pretend that that's where we are, so that we can have a conversation among ourselves. And then later, we'll open this up to the audience. So I'm going to start by posing a question that Larry, you've raised. But it's not only for you, so have this as a discussion. And then I have later questions if we get to them.

So one of them has to do with generations – cohorts. You are dealing with younger physicians and other clinicians and older ones, just as you were starting to talk about at the beginning of your presentation. And, you know, they use technology so differently. So, for example, they'll see the guidelines in clinical decision support as rules, not tools. And that's something that I know concerns you. Yet another example might be just even the language people use. Somebody's younger, they're liable to say something like, "OMG," or some other phrase. And yet, you're having to use in your projects, natural language processing. But boy, do we have different languages, now. So could you start out by talking about some of that?

Larry Norton: Well, number one, we have to avoid abbreviations. That's one of the greatest dangers. And I've actually seen patients harmed by – there's a certain way that developed in Boston of looking at blood counts, red cell/white cell platelet counts, by drawing a little figurine and putting

numbers in that figurine. And it evolved in the Boston hospitals, and was always regarded as really cute. And then what happened is that different hospitals started putting different numbers in different spots in the little figure, but they knew it because they were all within the hospitals. But when they went on to different hospitals, other physicians looking at that, saw the platelet count and thought it was the hemoglobin, and made decisions that were really very dangerous. So in noticing this I went totally insane and totally prohibited all abbreviations from the records.

An interesting point in this regard is that, now that we're doing the Watson project, now that we're involved in this Watson project, because we can enter our data in verbally into systems, or we're working that way, it actually it's faster not to use abbreviations than to use them. Abbreviations, to some extent, are an artifact of the old method of keeping records, which is a pen and a piece of paper. So I just want to make that point. But I also want to make a bigger point, which is that I, myself, am dictating my notes differently now, then I did before we started this project, because I know it's going to be read by a machine. And so I have to have certain clarity. And so I find myself, sometimes, whereas I used to just basically talk into the machine like I was talking – like I'm talking now, I'm talking to people, assuming you're going to sort out what I really mean, and I have to think about what I really mean before I say it.

So I'm seeing a co-evolution of our project and my ability to synthesize information before I record it. And I'm just noticing this in myself. And so, you're talking about the younger physicians and the younger people in general, they've grown up with a certain kind of technology, and they have co-evolved with their technology. Their thinking patterns and their approach, really, to information is really based on that. You'll notice, when they watch television, there's no such thing as just a person talking. There's things going along the top and the bottom and the sides, and things popping out, because they've learned to process information that's coming from multiple sources simultaneously, and that's the way they learned it.

And so I think the educational process is going to have to take that into account, and is going to have to train them from a very early stage about how to interact productively with these systems. So what I mean, productively, I think the biggest danger is what you said before, is the computer driving the car, rather than giving you information and letting you make a decision to drive the car. I think this is a huge danger. I think what's going to happen is we're going to make bad mistakes in this regard. And I hope that according to those curves, that we're going to overshoot, and we're going to correct, and come out with something really right in this regard, because I, myself, I'm seeing some physicians that are either rather mature right now, taking histories from patients, and never looking at them, only looking at the computer screen while they're

typing something in. And, "Please tell me about your sex life. Are you having erectile dysfunction?" Is not a good way to communicate? And I think that the – that doesn't apply to me, by the way. I just wanted to make that clear. *[Laughter]*

And so I – the bottom line is I don't have the answer to this, but I know we're dealing in a period of co-evolution where the machines are changing, but we're going to have to change to be able to keep the art of medicine and the human part of medicine alive as we go through it. And I'm just mentioning it to this audience, because I think this is something that's going to be really critical for us to keep in mind as we co-evolve.

Jeffrey Lerner: It's interesting. One classic aspect of this is in the pharmacy area, where you have similar sounding drugs, which has normally been a problem for patients' safety. So now, doesn't that get compounded when people are dictating using these different languages? What do you think about that, Troy? Is that a real issue, or am I making things up?

Troyen Brennan: No, it is a real issue. And there's a series of efforts underway to make sure that things that come through from e-prescribing are coming through safely. We've done some research recently where we looked at things that came from an EMR and things that didn't come from an EMR. And you'd expect the EMRs to be basically having some filtering function. And I turned out they were no safe. So we're failing there. I think there on a big data point of view, though, along those lines, what I would outline would be what we call DUR systems, Drug Utilization Review systems, which are – have been in place for 15 years, and there's a couple of big companies that sell them to us, and our insurance is based on using them. And they basically look at all the potential interactions that occur between people's drugs, and then provide warnings for the pharmacists.

But those same things are available on some EMRs. Most of the physicians who are on EMR shut them off. A lot of pharmacies shut them off. We run them on our retail pharmacy, and we also send them from our PBM. Our own retail pharmacy shuts off our PMB one. The IOM has looked at this and said, "You know, this is an example where there's way too much information coming through." So, it just turns into noise, because they produce so many potential interactions. So we're in the process of trying to decide, using relatively advanced analytics, how you change the frequency on the predictive analytics, basically trying to move towards greater sensitivity, or greater specificity. And it turns out, and the IOM has agreed with this, it'd be much better to concentrate on the top 30 drug utilization interactions and really address those, than addressing the thousands and thousands that are coming through. So it's a good place

where simply being able to produce data doesn't produce good outcomes.

Jeffrey Lerner: Well, it's a very interesting – By the way, that discussion of extra data, or what sometimes – what Brent James has called recreational data – is going to come up later in this conference. But it is a very interesting issue. George, do you want to comment on this particular issue?

George Bo-Linn: Well, I'll pick up the issue of generational and non-erectile dysfunction. Although I could do either one. The generational issue, it is an interesting phenomenon that we take people who are normal in activities outside of health care, and then we bring them into health care, and we suddenly dehumanize them. Same thing. Let's go through a couple of things. One is, currently the fastest growing segment in the use of smart phones and purchase smart phones are so-called older individuals. The increase – we've moved way beyond texting while driving, that first you put on makeup while you're driving, then you're eating while driving. Now you're texting while driving. But now people curating, re-curating their life history on Facebook while driving. And that's an increasing problem amongst the elders, because the older generation is coming to Facebook. I know that because my kids are leaving Facebook.

As a consequence, then, we have the unusual situation where you take digital natives, the current students that are coming in, and we try to move them away from being a digital native, where they spent all their time texting, to spend time with the patient. And we're taking older physicians who spent all their times running away from data, everywhere, in the hospital. But outside, physicians use smart phones all the time. So it's an interesting paradox where in health care we seem to consciously distort reality. It's like a continual distortion of reality machine. We take young people, and we try to turn them into people, and we take older physicians who are people, and we try to turn them into augmented, intelligent, robotic executers. *[Laughter]*

Therefore, I would say the following. One is that we must begin with the reexamination of graduate medical education, graduate professional education throughout – pharmacists, physicians, and nurses – to understand, not the technology, but rather the value of knowledge, of intelligence. Second, we need to bring patients into the conversation, so that patients who are equally adept at bringing in reams and reams of the Internet delineation of their particular disease, to try to understand how it can bring in some augmented intelligence into that conversation. By bring in physicians, patients, together – clinicians together – I think that we can better understand the use of technology without the seduction of tools, tricks, and devices.

Jeffrey Lerner: So I have a variation – just a question on – that's somewhat related. Larry, you talked about the international aspects of data. And as long as something is published in English, you can process it through Watson. But one of the great tools in medicine is, of course, not just the articles, but are they clinical histories? The same sort of information that you are also processing as you're tapping the intelligence, the experience of your physicians at Sloan Kettering. But what happens when the data is coming from around the world? Somebody speaking in Chinese, a language that doesn't translate all that easily – certainly not one for one – with English, or any other language, some closer, some more difficult? How's that being dealt with?

Larry Norton: It hasn't emerged in my world. I'm just talking about oncology. So I'm just saying, that as a big problem, since all of the major meetings, and most of the minor meetings are in English, it's become the lingua franca. I was interested in Esperanto when I was young, because I thought that really, world peace would only come if we were all speaking the same language. But to some extent we are. And English is a very good language for technology. It takes you twice as much space to say the same thing in German as you could say in English, when you're talking about a situation. I was impressed with this actually years ago, more than a decade ago, when two colleagues of mine – I was at a meeting in Europe, and two colleagues of mine who are both Italian, were discussing a case in the corner just between themselves, and I overheard them discussing the case in English. They would order their wine in Italian, and they would live in Italian, but they would discuss the case in English, because it's just much more efficient to do so. So it really has not emerged as a problem in that regard. And so I think we're probably going to have to stay in English. Most of the major journals are in English. We do translate them into other languages, into Mandarin. We have a Spanish language version. I think the – But those are issues that we have to address.

Fortunately, I think that the Romance languages are consistent enough that we can make sense. I don't know enough about the Asian languages. And we actually have a task force that's actually thinking about that at the present time. But since the Internet is largely English, that probably – we're just going to have to make a universal rule that the information is going to have to be processed really that way.

In terms of this generational thing, because I want to get back to it, that we made an early decision with the Watson program, that the Watson machine wouldn't say, "Do this." It would say, "These are your options. This is our summary of the evidence presented as a level of confidence,

really based on the evidence." And our plan is, in terms of teaching people how to interact with this, is to basically, on the basis of the information that we get, and contact with the patient, the machine would come back with certain recommendations. And then there would be discussion with the physicians in training, with the more senior physicians. And the patient's a really very important part of that is that hair loss is a big deal for some people, and not a big deal for other people. And that has to be taken into account.

And there's something in the pharmacy area that's very interesting, is there are – it's kind of the inhibitor. There are three of them that are really equivalent in terms of efficacy, and variations I toxicity, but it varies from patient to patient. And the decision was made that, in terms of our buying capacity, whatever, that it might be better to make the decision on the less expensive one, rather than others, and then negotiating the price and all the usual things that happen in a situation.

But you talk to a patient, and you start to talk about the situation, and she says, "Well, whatever you do, don't start me on drug B, because my sister had drug B, and then she died." He says, "No, no. I was actually thinking of drug C." Now that's not something that's going to appear anywhere in the machines at the present time. That's a human interaction, and it's a subtlety that you have to take into account when you're prescribing medication, so that when the recommendations come, it becomes a point of discussion. And I could actually enter into the machine. I'm prescribing C instead of B for this reason. And then that becomes information that the machine could use in terms of subsequent decision making. And we call that patient preference, that's the name of its category.

So that we're basically teaching the machine the same way we would teach a fellow. And the fact that, because of the extraordinary advances IBM has made in this regard, we can actually teach him by saying in English, "I am prescribing C because the patient doesn't want to get B, because she knows somebody who got B and did not do well." I can say that, and the machine will actually understand that, because the key words really are there to understand it. And so it's an interactive process that has to be taken into account. And I think at the pharmacy level it's going to be very important. There's a movement afoot for pharmacists to be able to substitute drugs of equivalent activity under certain circumstances. And I think that that doesn't take into account what I just said. So we're going to have to learn how to use that information.

Jeffrey Lerner: Fair to say that some of what you're discussing, when you talk about the technology, are essentially emergent properties of the machine. So I'm going to ask some of our other colleagues to discuss that. How close are

we to really understanding emergent properties of these machines in medicine?

George Bo-Linn: I don't know. I guess that's why they're called emergent phenomenon. I would say that, if I wanted to find out about what's going on in technology, I'll go to three places. I'll go to *Wired* magazine. I'll go to Google. And I'll go to smart phones. And fourth, I'll ask my kids. So, I would say there are four considerations of emergent phenomena which I think are quite amazing. The first is the infinite capacity for data ingestion. That is an extraordinary opportunity. That way there is no wasted data. There's continual reuse. I mentioned that the number of misspelled words, in fact, could be considered to be wastage. But, in fact, when properly applied, it becomes the predictive text. The number of key words that are often repeated in languages could be just wastage, because then you have to convert it into English. But then it could be, in fact, the driver for translation, which is, of course, what Google uses.

The second thing would be the power of predictive analytics. The larger the data sets, the more often the greater the machine learning, the more often the more accurate is the predictive learning.

Third is the opportunity to understand correlation as compared to causation, the sort of things that you mentioned. I think we've never been faced so deliberately with trying to understand what is a correlation that defines reality, as opposed to a causation, which remains elusive.

And the final thing is the machine-human interface. There are actually – because my nephew took that – there's a major now in machine-human interfaces as part of computer science at Carnegie Mellon University. And I think that's the fourth emergent phenomenon. I'm not talking about technical phenomenon, because we have technicians that'll do that. In health care, I believe that we should not get involved in the technical components of the machines. I think we should try to figure out how do we apply them to the practice of medicine, which by nature is a human-human activity augmented, perhaps, by intelligence that we receive from machines. I'm always focused on the application of emergent phenomenon in machines.

I think we also have some people in the audience.

Jeffrey Lerner: Yes, we will. Definitely. If you want to comment on this, we could break with the normal set. We were going to open this to the audience for 20 minutes in about 5 minutes. But if you're on this topic, why don't you join us.

Ted Palen: So I had two questions. This is Ted Palen from Kaiser in Colorado, and I'm over here on this side. And one is it intrigues me about the wastage of information. You talked about dictation. But in a lot of medical records it's templated – right? – and you're using a template and choosing an active descriptor embedded in that template. And in come case the other verbiages in the template could be considered wastage. But how do you decipher the activeness from the wastage in the template. And the other thing is we've been – my second question is, we've been looking at really health care or provider centric information here in the last hour or so. We don't want to lose sight of all that information that the patient holds. And I think of it – I like a term that the providers in Canada used on this is, bringing the patient to the PROM, Patient Reported Outcome Metrics. How do we bring the patient into this PROM – into our knowledge? And how do we utilize all the richness of data that they possess as they're trying to manage their own disease process?

George Bo-Linn: If I may be so bold. So the Gordon and Betty Moore Foundation's theory of action is that we aim to eliminate preventable harms by focusing on, and meaningfully engaging patients and families in their own health care within a redesigned, supportive health care delivery system. The redesigned health care delivery system is our big focus on technology, whether it's big data and algorithms driven to predictive analytics, or reconfiguring the processes through a systems approach of engineering. That's hard.

The harder one is by focusing on and meaningfully engaging patients and families in their own health care. We believe that there are three vital things that we're working on. One is the means by which we bring them into conversation. We believe that that can be technologically enhanced. So we are actively designing, now, with Hopkins, Beth Israel, Brigham and Women's, and UCSF, building digital tablets in the ICU to bring patients and families actually into dialog on such critical considerations, such as how do you see the end of your life? And what is the definition or the consideration of futile care? We believe that bringing them into conversation means that they are already technologically aware, such as e-tap, which is the way to do that.

Second is to capture that. We believe that capturing that through micro blogging – which is an activity that David Bates is working with us at the Brigham and Women's – is critically important, because then we get the voice of the patient and the family, particularly the family, and the extended family, and capturing that as unstructured data in a database where storage is not an issue, is incredibly important.

And the third component is changing care processes based upon the input of patients and families, particularly in the intensive care unit. We picked the intensive care unit because it's a contained area in which we can do experimentation – quasi-experimentation – but it's a quick cycle time, high expense, high consequence, and very intact management and clinical teams. And so by bringing patients and families into the ICU where they are most often alienated, tragically, we hope to bring voice to the patients and families.

Those are some of the things we're working on at the Gordon and Betty Moore Foundation.

Jeffrey Lerner: Ted, did you have follow up, or you good?

Ted Palen: That's fine.

Jeffrey Lerner: Okay. Let me stay on this –

Larry Norton: I don't want to hog all the time here. I want to hog most of the time but not all of the time. Just in this kind of issue, in oncology, patient's perceptions are extremely important for decision making, if you're trying to avoid toxicity of medications, for example, and modulate them. And so, many of the same things – and I want to talk to George more about what he's doing, because I think it could be brought into the out-patient oncology arena just as well, perhaps as in the ICU setting – that we find that tablets are the way to go. An enormous amount of information can be gathered. But it does have to be processed through an expert to really interpret what people mean, because sometimes adjectives that are used are just not representative of the reality. But that it's a very important part of the process. And how to use that properly is as important as everything else that we're talking about.

Jeffrey Lerner: Before we go back to the audience, Troy, I have a question about this. It seems to me, based on my extensive study called anecdotally driving around Philadelphia, that there are a lot of drug stores throughout Philadelphia, including the areas that are, quote, under served. So, do you see any difference – is there anything in the data you collect that shows in any of your sub groups differences in underserved populations? Are you looking at that in any organized way that would address this issue of bringing the patient in?

Troyen Brennan: Well, I don't think necessarily in terms of addressing the issue about bringing the patient in. It's fairly clear that people in underserved areas get less good health care. And that doesn't necessarily mean that they're not on the medications that they should be on. A lot of times you just see that they're on unbelievable amounts of polypharmacy. So if you look at the dual eligible population that qualifies for both Medicare and Medicaid, and includes a lot of people who are poor and stuck at home, and very low functioning, those individuals often have the biggest problems with polypharmacy, compared to anybody else.

We also find more and more interesting things about the interaction between ability to pay and race and socioeconomic status. So, we've got some papers that we're about ready to publish where we're trying to help explain why it looks like there's poor cardiovascular outcomes in people of color. Well, one part of it is that those populations are especially sensitive to anything where there's high deductible health plans involved. They just simply don't buy their medications. They don't follow up as they should.

So, there's a lot of analytics available. And one of the good things about our particular industry is that we are in a lot of areas. If you go into many impoverished areas in American cities, some of the few mercantile stores that you'll see will be us and Walgreens. So we feel like we have a role to play there. But some of the things that you find are sort of surprising. And for me, people on too many medications, rather than not on the right medications is an interesting one.

Jeffrey Lerner: That really is interesting. Are there also communications issues, anything different in terms of dealing with patients in those underserved areas? Or is it really just more economically driven?

Troyen Brennan: I'm sure there's communication failures, but it's not something that we're actively studying. What we can show is that if you've got higher levels of engagement with your pharmacist overall, your care is better from a pharmacy point of view. And so we spend a lot of time trying to think about that. But I don't think that differentiates us at all from the rest of the health care system. I think that these problems with communication are both rife and fairly ubiquitous.

Jeffrey Lerner: Yeah. I've been wondering, though, if there was some way to study that through the use of this more sophisticated data. But let's take this back to the audience. It is time. So please. And tell us who you are.

Michael Floradis: I'm Michael Floradis, Baylor College of Medicine. And Jeff, my complements for this session lineup. A great kick off. This has been a tremendous set of presentations and discussions.

Jeffrey Lerner: Thank you, Michael.

Michael Floradis: I have a question, really, about the quality of evidence, and then moving that ultimately to the physician/patient conversations, and ultimately shared decision making, and maybe Dr. Norton, and Dr. Bo-Linn, I'd love to hear their comments.

The first issue, in terms of the quality of evidence – and you talked about the quality of recommendations. And certainly there's a lot of effort going around in this whole area of evidence synthesis, and rating the quality of evidence. So I wanted you to say a little bit more about, as evidence comes in, how that's handled, in terms of assessing the quality that helps you get to that rating for the recommendations.

And the, with that, because we often see a lot of uncertainty, as we all know, in evidence. And when we take that to the patient there's issues of how those are to be handled, and the explorations of values and preferences. And sometimes that's done in a really very detailed way. And it seems like there's opportunities to learn about the values and preferences of a patient in terms of informing other patients in the future. It's almost like "People who bought this book," you know, "bought that." And I just wonder, are we at the verge of being able to use big data to help patients inform the directions they might take?

Jeffrey Lerner: Go ahead, George.

George Bo-Linn: Okay. Those are big questions. I'll leave the evidence to Larry, because you clearly have to provide some direction to Watson.

So let's talk about the opportunity of big data in understanding the wishes and values of patients and families. When I stated the theory of action of the Gordon and Betty Moore Foundation is the aim of eliminating preventable harm. Including in that would be not just medical harms, which we all know so well, infections – bloodstream infections, DVTs (deep vein) thrombosis, and PEs, and such – those are pretty well known medical harms.

The harms in which we are equally focused are the so-called non-medical

harms, as though they were less consequential. And those are the loss of dignity and respect, and care that's inconsistent with wishes and values of patients and families. We believe that those are as real, as measurable, and as preventable harm as it is to have a post-op infection. Therefore, we're developing new measures to understand what those mean, from the viewpoint of patients and families, as well as developing interventions that we believe would be promising. This is particularly in the ICU.

We're also working with Penn – University of Pennsylvania – Scott Halperin to look at then how then do you present – just take one example – how then do you present the consideration of advanced directives in the intensive care unit setting, which is oftentimes beset by emotional considerations, as well as families that may not have, in fact, functioned as a family for some time, coming to some understanding of what are the wishes of patients and families. In that we're bringing in the components of behavioral economics, as well as the consideration of cognitive functioning, so that we can present information to the patients and families in a way that they can come to an informed decision about end of life care.

From that we hope that we'll be able to understand three things. One, when do you present such information to patients and families, that would be captured in unstructured data? How do you present it that would be captured in unstructured data? Pause. For example, we're looking at sensor data to measure the length of the conversation, the tone that's used, and the volume. And we can actually – this is work we're doing with the computer science department of Johns Hopkins. You can actually determine by the tenure, the tone, the volume, and the length of the conversation as to the value of that conversation that would be captured in unstructured data. We'll be able to teach, in fact, in a real way, how to communicate with patients and families, from the viewpoint of physicians, rather then, "Oh, you need to be more empathetic." I don't know what the definition of empathetic is. But it would help me to learn that and, in fact, to hone that through feedback, again, using machine learning.

And the third component is to capture then, how the patients and families feel about it. So we have some longitudinal studies to try to understand how patients and families. We, of course, would crosswalk that against the various demographics, the considerations of the family dynamics, which we would hope to capture, as well as the considerations of the generational issues that come up in patients and families. All of those, because we're not constrained by data storage, now. And now, with the value of NLP, Natural Language Processing, we can better understand, not in an observational way, but in a more scientific way, what is the best

way to engage in conversation with patients and families, that accomplish the purpose – understanding, correct decisions, and appropriate action.

Larry Norton: That's fantastic. And I think I can't add anything to that. I'd like to learn from it. My favorite empathy story is where, I had a clinical psychologist who was actually in the hospital who – a young physician who was counseled on being empathetic came in and said, "Listen. I know what you're going through. You're going through a very tough time, because my mother had the same disease that you have." And my patient psychologist said, "And how did she do?" And he said, "Well, she died." *[Laughter]* And then – So actually we engaged in a discussion. And he really thought he was being empathetic. He thought he was being kind, and being very human about it. And I don't know how you'd measure that, necessarily. It was, obviously, a very stupid thing to do. And the word stupid has to have a quantification on it, I think.

But in terms of the confidence of the recommendation is based on the machine's confidence in the recommendation based on the synthesis of data. And if there are conflicting ways that somebody should be treated, that's going to lower the level of confidence that the machine is going to have in making its recommendation. If 100 percent of the input – somebody with a tumor gets a hormone disturbing drug, everybody's going to do that, the machine is 100 percent confident that that should be done, but may have some lower levels of confidence about which drug to use, and may be appropriate in that situation.

But the important part of what we're doing, and something I feel about very strongly in this is that the machine learning has to involve a human interaction, so that there's the hard data, the information, most of which is going to be entered directly into the machine without actually passing through human eyes in this regard. It's available to human eyes, clearly, and we look at it. And then the machine comes out with a recommendation. And then there's a discussion, not only with the patient, and with trainees, but also with the machine, saying, "Machine, you gave me 97 percent confidence that this is the right thing to do, but boy are you wrong, and this is why you're wrong." And so the machine can learn, really, from us. And, of course, ultimately we're looking at outcomes, how well the patients do. Did they respond? How well did it respond? What were the toxicities? What was the cure rate? And so on, because that's going to teach us what is the best way to proceed.

So it's a co-evolution. I think the key thing that I've learned from this whole process is that we can't say, "We have the wisdom. Let's put it into the machine." The machine also has its own form of wisdom that we're going to have to learn from. And we're going to have to learn to think – be able to use the machines better. The machine's going to have to learn

how humans think and learn these other factors. So I think we're in a phase of co-evolution with these machines, and we're learning how to use them.

Similarly, I've got this gizmo here *[holds up smartphone]*. I used to try to memorize things. I used to try to commit to memory certain things. I don't do that anymore, because I know I can get the answer much faster form this than I can from my brain. And I learn how to search for information really efficiently. So what I've learned is how to use this machine to get information very quickly. And that was something I had to learn rather than memorize things that the machine memorized better. So my own thinking in many areas, in the arts, for example, what other plays has this actor been in? I don't have to rely on my memory for that, so I don't bother memorizing it. I just know how to find that information very quickly. So there's been a co-evolution in my thinking process because of the availability of the machine. And this is exactly what's going to have to happen in health care.

My only comment on this is that we're going to have to maintain the human interaction between the doctor and the patient, the nurse and the patient, and not let the machine substitute for that. And I think that's going to be the biggest challenge we have to face.

Jeffrey Lerner: Want to come back on that, Michael? Or you –

Michael Floradis: Well, one quick thing, and that is this. You've touched upon an extremely important point here, and that is when we look at evidence, particularly in our RCTs, we have challenges with applicability. And this is the opportunity, really, in which we can examine that applicability. And that sounded like that was a subtext in there. So that we're looking at pragmatic trials, and other ways of do this. And basically, this is another tool set in which to do that.

George Bo-Linn: I would say that the opportunity in big data – because I was in clinical research for a number of years before I did other things. What I was trying to do, most often, in many of the studies was to create an artificial environment by which I could test truth, and often late in the – early in the morning. Truth doesn't come easily. And trying to create that distorted environment by which I could define truth oftentimes led to an artificially constructed truth, which in some regards could be randomized control studies, where you try to eliminate as many confounding variables. And that's even before you get to statistical analyses.

The opportunity of big data is that you don't have small data sets. You

have, in fact, all data. And with all data, then, the opportunity to create understandings of truth become much more real. And again, what I would say, the opportunity of big data gives us the challenge of understanding what is good enough correlation between causation. All data is liberating, because what we're talking about now is data liquidity, complete and total data liquidity.

Larry Norton: George, can I ask you a question? Is this permissible, Jeff, or not? Can I ask a question, or would you rather –

Jeffrey Lerner: Okay. Well, let's try and do one more – but let's also remember we have other people. But, go ahead.

Larry Norton: Yeah. Hormone replacement therapy in post-menopausal women, all the observational data available would have led us into the wrong conclusion. And it did, and for many years. And basically, the observation was very clear cut is that women who took hormone replacement therapy did better in all parameters. And a randomized clinical trial showed it was just exactly the opposite. But the reason the observational data wasn't – didn't show that way is because healthier women tended to take higher socioeconomic groups, and healthier women took care of their health in general tended to take hormone replacement therapy. It actually hurt them, but still they were above people who weren't taking it because they started off healthier. And I'm very – I still think there's going to be a very important role for randomized clinical trials, which is the artificial environment you're talking about. I don't think we have to totally abandon that.

George Bo-Linn: I don't mean to be binary, although this is a data conference. *[Laughter]*

Jeffrey Lerner: Okay. Let's take our next question.

Jeffrey Lerner: Tell us who you are.

Rory Jaffe: Rory Jaffe, California Hospital Patient Safety Organization. And dealing with lots of – tens of thousands if not hundreds of thousands of written reports. And big data – In a lot of other industries, technology is the main interface that effectuates that industry. You can instrument an air traffic control system in the planes very well, but with medicine you are dealing

with humans feeding in a lot of the critical data. And when I look at the data I'm looking at, it's more like big data equals bad data. How do you set up an infrastructure that allows you to clean this up en masse? You're dealing with, for instance, electronic health records that have had cut and paste errors. You may be dealing with a clinic that doesn't measure their blood pressures the same way you do. You may be dealing with research that is mostly funded by drug companies, and so is focusing on particularly expensive and new drugs. Where's the infrastructure to clean this up? Or are we just – am I asking this too early in the process?

Jeffrey Lerner: Well, that's interesting. Troy, while there might not be a complete infrastructure – as there never is in the US health care – does business, large business, provide a large chunk of that infrastructure, for that issue?

Troyen Brennan: No, I don't think so. I thought I heard the question sort of how do I deal with this sort of unstructured data I've got coming through on patient safety issues. And I think that's very difficult. Having been in the patient safety venue 20 years ago, that was the ultimate problem that we ran into in terms of being able to identify and process injuries that were being caused by medical care. But I think that the answer is somewhat not big data, but little data in that regard. The big interventions that I've seen and have really improved patient safety over the years have been basically the efforts originally in Michigan to make sure people were washing their hands appropriately and putting in lines correctly. And then simple use of really very highly structured, but not complicated check lists in the operating room. So, those have been the interventions I've seen over the course of the last 20 years that have really worked. And I think what you're looking for, you're trying to pay attention to the data that's available, but you're looking for relatively straightforward insight. So when I think about patient safety from my point of view, I want to redesign the bottles and put much simpler labels in place. I think that'll really reduce the number of errors that occur. So, in many ways, the simplification may be built on a lot of analysis of existing data, but nonetheless getting simpler rather than more sophisticated.

Rory Jaffe: But I want to back up from the specific topic of patient safety to really how do you handle this data, because we are finding that what comes in is often incorrect. To give an example, we're looking for health information technology related errors. Virtually none of those are classified as heath information technology errors. And so when – until you read it very carefully. The point is that if you look at your electronic health record, you look at anything that people are putting in, you look at what the patient's are putting in, there's a tremendous amount of chaff with a little bit of

wheat. And the question is, how do you clean it up, or what should we be doing to the way we're collecting data in our electronic health record, in our pharmacies? Asking patients for their allergies, for instance, and getting all sorts of funny answers. How do we work to clean this up so that we do have usable data? Or are we going to end up with a Wikipedia where some of the entries are very good and some of the entries are completely wrong, and it's impossible to tell the difference?

Larry Norton: Just a quick answer is first of all, what we found is cross checking. The tumor's S receptor negative but that's incompatible, so that's a signal to go back and actually look at the original data. So that's one thing in that regard. The second is that that's one of the advantages of big data, is that those kinds of errors, if you're trying to get information about what is appropriate therapy, the little errors are relatively rare. And as long as you're capturing enough data it's going to – it's going to eventually wash out. And so – because it's just going to be a blip in terms of looking at the overall thing. So those are two things that we're hoping for. But you're raising a very important issue.

George Bo-Linn: In my conversation I mentioned about before we get to data hygienists we need data janitors in health care. I certainly sympathize and agree with the conundrum of the disarray in health care. We have no standards. We have no common definitions. In one of the projects we're working on in the intensive care unit, we have a variety of monitors, all disconnected, we have enormous technology that is isolated, and no integrated viewpoint. Our desire is to create that data and pull it into, including unstructured data form the patients and families, as well as clinical processes, which are, you know, are not captured in standard language, is to move to data visualization, situational awareness and control, embedded decision support. And then what we hope to do – and certainly we would never do it without talking first with the FDA – about closed loop systems.

In the question that you asked, I think that there are two considerations. One is that, in the – is to coming to some understanding of the use of meta data tagging. So, if we're capturing physiological data in the ICU, one of the things that we're trying to understand is, how do we capture simple waveforms, which exceed the capacity of your servers, which means you have to move to cloud services? Then, in capturing the waveform, for example, if you want to look at something simple as blood pressure, the cystoloic and diastolic usually measured in millimeters of mercury, what do you do with mean arterial pressure, and how do you relate those?

So what we're trying to do is to try and understand how we can apply

meta data tagging, which is not the actual element themselves, but in order to tag that element, and then to apply algorithms at a later time. Those same questions are being addressed in numerous other industries. Applying it to health care is new, but what we're hoping to do is to try and understand how you clean data, absent standards, by bringing in tools, of being able to evaluate enormous databases, structured or unstructured, that do not have currently standard of the syntactical harmonization with what we're talking about. As opposed to WBC, as opposed to a leukocyte count. All of those things can be evaluated. And what we are looking at are the various tools available outside of health care to apply them to data liquidity inside health care.

These are all enormous challenges. But what I'm saying is that all the questions that we're asking are already being asked, if not answered, by financial services, retail, the Department of Defense, DOD. Those are available in various ways, now. We just have to move outside of health care and understand what we can bring into health care for the full use of big data.

Jeffrey Lerner: Thank you. I know you have questions. Sorry.

Jeffrey Lerner: I'd like to apologize to the other questioners, but I actually do have to close this session. So I would like to ask if, during the break, which we're about to take, you either your question privately, or come back to the microphone in one of the subsequent sessions earlier. And I'm sorry we can't do all of the questions. But so. My apology.

I'm going to just close down the session with one quick reference. When we were preparing for this session over the phones among the speakers, we dealt with health care, but we also dealt with baseball, and found out, in the course of that, that Larry was a particular New York Yankee fan of a particular era. So here's how I'm going to close this session.

It's all about New York baseball. So here's how we do it. First of all, this is for Larry. He's the Yankee fan. And there's two other aspects to New York baseball. One is that there was one team that's on a brief road trip from New York. People from a New York of a certain era know that they're only temporarily gone. Here you are, George. And, of course, there's the current world champions, *[Laughter]* – now just a minute, just take it easy. There's the current world champions, and New York baseball fans would like to thank them for selling Babe Ruth to the Yankees, the greatest trade in history.

Okay. So, thanks very much. And again, questioners, please come back for the subsequent sessions. Thank our panel, please.

SESSION 2: INVESTING IN BIG DATA: THE VIEW FROM THE HEALTH SYSTEM C-SUITE

In determining whether big data are affecting health systems, it is essential to understand what data the c-suite leadership are using. This session features chief executive officers of major health systems who will discuss what data they use to inform their decision-making processes.

Speaker/ *Moderator:* **Ralph Muller,** Chief Executive Officer, University of Pennsylvania Health System

Glenn D. Steele Jr., M.D., Ph.D., President and Chief Executive Officer, Geisinger Health System

Gary Gottlieb, M.D., M.B.A., President and Chief Executive Officer, Partners HealthCare

Jeffrey Lerner: Okay, so now we're on to session two. And I'm going to make this an extremely brief introduction, it goes like this: did you ever wonder what the CEO's of health systems think about data and big data? You can stop wondering now. The speaker/moderator for this session is Ralph Muller; he'll take it from here.

Ralph Muller: Thank you, Jeff. Good morning, all. I'm from the University of Pennsylvania Health System and to my right is Gary Gottlieb, the CEO of Partners and I used to say Boston but now you're all over Massachusetts so I'll just say Boston and Massachusetts. And immediately to his right is Glenn Steele, the CEO of Geisinger and I used to say Pennsylvania but now he's in a couple states as well so these health systems are expanding.

We decided to not do PowerPoint's, to just have a conversation so you'll have a chance as well to. No, I must say, the previous panel did a great job so I was very impressed by what they did but we thought that having a conversation among ourselves and then a chance to really interact with all of you would be a good test of how this program goes, so see how it, we'll evaluate afterwards how well it is.

So I'm gonna start with a broad question to both Gary and Glen and they can then have a chance to weave a little description of their organizations as well which may be helpful to you, especially since these organizations are expanding and evolving seemingly day by day. So I'll start with where is big data being used inside Partners and Geisinger? And then maybe along the way as you talk about that you can give a brief description of where Partners and Geisinger are, especially as they're evolving both geographically and progamatically so much. So Gary –

Gary Gottlieb: Sure, thank you very much and I was very impressed with the panel and I think that many of the warnings that were created and described by the panel members about the collection of data, accepting those data, having to both cleanse and tend those data before making conclusion about those data are pretty critical and that data big or small, are just tools and from our perspectives and the perspectives of all three of our organizations, tools that enable us to do the tactics that support the strategies that support the

> missions of our organization. And for us I think that there are several dimensions in which we've become increasingly driven toward trying to accrue data with the belief that it'll better inform the way that we perform or allow us to move into areas of the work that we do that better enable our envision going forward.

So one, in, to some extent in an older sense Eugene Braunwald, when he was the Chief Academic Officer when he was at Partners together with Sam Theer, created probably about 12 or 13 years ago a research data patient repository for Partners where basically all of the clinical data about our patients in and around our system in our ambulatory sites and in our hospitals ultimately became and what has evolved to be a very important phenotypic database describing a very broad set of dimensions around our patient population that have been used pretty extensively now for the better part of a decade and half in being able to identify patients who would be eligible for clinical trials, to be able to do some post-market drug surveillance and look specifically at adverse drug responses in patient populations, to be able to identify cohorts of patients who have had a singular clinical experience and a specific intervention to be able to determine what outcomes were associated with that. We've extended that as we've started to move toward high-precision medicine over the course of the last five years to be able to correlate those data with data that are in bio-repositories of one kind of another. First, you know actually going back to the descriptions that were mentioned before about discarded data, we started to take a look in, to characterize discarded fluids and put together a specific project called Crimson in which we could correlate those phenotypic data specifically with data that were identified, with tissue data from blood and other samples to start to work toward being able to have a higher degree of certainty and have tissue information, together with phenotypic information both at the population level and then at the patient level. And to some extent to specifically be able to look and inform clinical decision making really with the hope, you know, that someday we'll be able to move away from a system that's driven towards a hypothesis testing, looking for true negatives as opposed to those that start to look for true positives.

That database was then used as an infrastructure by a brilliant set of investigator named Zach Cohen who put together a project called I2B2 that then started to go to our electronic medical records and use natural language processing to actually use and look at the clinical descriptors associated with specific clinical conditions so that we could understand in an ongoing way what we're doing right, what we're doing wrong, what our patient conditions are, and identifying patients who are appropriate either for research or for improvement in clinical circumstances over a period of time. So that's an older set of work that's been going on that we're building on for a period of time. In some way it's a large data set and it has enabled the work that we've started to do, obviously in genomics, proteomics, and in other related areas where again the notion of just seeking big data has shown us that we're looking in the wrong direction where we can just sequence everybody and where we believe that doing geewaz would be science as opposed to generating hypotheses and then using the data that are

associated with finding genelosie and putting them together. So that's an area that has been important to us and that also been critical in the way we've looked at clinical data.

In the clinical data side we've been, you described the size of the system so, you know, we have about 10 or 12 different hospital locations, about 6000 some-odd physicians who are in the system in a variety different sites and each of them has been collecting data even in the areas in which we have uniformity in a variety of different ways without any consistent data governance, without a systematic way of collecting those data. And we found ourselves over a period of time having disparate data that take a long time to be able to analyze. So as we go into looking at trying to reduce costs or to improve care or to create seamlessness of care, to try to design more appropriate ways of managing episodes of care or ultimately now to managing populations. We have a set of data sources that are not only a little bit confused but certainly inefficient in that regard and that inefficiency is very costly in terms of, frankly, not having a single source of truth, not having, being able to give our analysts as well as our investigators, clinical leaders and managers, the kind of data to be able to inform decision making and to be able to access that.

So we made a set of investments to create a much more coherent set of data governance to create an electronic data warehouse that then creates data marks that are more easily queried for those analytic purposes. And for us it comes into a couple of categories; over the past couple of years we moved several of our commercial, Medicaid and as a pioneer ACO of our populations, into risk contracts so that, really to start to create incentives to organize care in a way, much more around our patients than around the transactions of that care. And as we've been reorganizing all of our primary care practices as well as our specialty practices, focusing on high risk and other patient populations, we've created a set, sets of programs to be able to profile and stratify those patients.

So first, the first way in which we've approached managing risk is to look at highest risk patient populations, you know the five percent of people that consume about 50 percent of the resources. We figure we got so many other things that we're not exactly right, if we can get that piece right, get the care around those people who we provide the most care to and for whom we've been doing a lousiest job of coordinating that care, we can start to both improve care, improve costs as well as improve the quality of care in a dramatic way. And we've created a couple of slices of that data repository to be able to look at: adherence to protocols, identify who's at high risk based upon previous utilization, and then create a set of standards that can inform care managers as well as physicians as to how to anticipate problems, how to work within those practices, to inform those practices, and also to figure out what resources we need within them, where do we need to integrate behavioral healthcare most aggressively and most effectively, where do we need to make certain that there are dieticians and pharmacists within practices to be able to reduce the variance in a way that might not be completely

standardized across the system. So it's starting to inform what we're doing, we're starting to use those data and we're starting to see some improvement in quality.

And finally, going to the last point around patients, we've started to create an automated approach to collecting a patient reported outcome data that's in an experimental phase, so that's small data to be able to be added to the big data and to use standardized assessments of functional capacity, quality of life, decision making capacity, behavioral health outcomes, mood, and other components and to integrate those around conditions specific interventions as well outcomes. So we start to move toward the notion of being able to measure the outcomes that patients want and be able to inform our providers about the needs of individual patients and to use the data in a way that we can collect to inform the system as to how to move itself and to improve itself.

Glenn Steele: First of all, it's a great honor to be here with Ralph and Gary and I look forward to the discussion. There were of things that came up and in the earlier panel that I think could probably be rediscussed here today, one of which is this issue of how data actually becomes information and how information becomes knowledge. And that's, it's a very interesting aspect of our system. We have, just to summarize, we have the perfect, the perfect experimental venue, if you will, for almost all stakeholders in a demography which is large but workable. We're responsible for about 2.8 million human beings on both the insurance side and the provider side; it's a very stable demography and over the last 10 to 12 years we've taken a non-proprietary approach to our data and data distribution as we're allowed, up to a Stark Anti-Trust. So we, you can understand then with that stable population with the ability to look at insurance company data as well as provider data, in a 20 year relationship with Epic, it, there's a huge amount that what we've been doing over the last 10 years is predicated upon.

The thing that drives our use of data and the thing that actually helps us create the right balance between simply accumulating data and not knowing what to do with it is the function that we're driving towards. Our system as opposed to where I was in Chicago and Boston, our system is really, because of the perimeters that I've just discussed with you and also because of the fact that we're not a medical school based, academic medical center, we train residents, we train fellows but we're fundamentally designed to look at health services research and to do in a way that can evaluate over long periods of time, can actually parse out both aspects of the value equation, both the quality as well as the costs aspects. And so over the last 10 years we have been programmed from the beginnings of our strategic aims, which is fundamental innovation to extract as much of the, what we believe is 30 to 40 percent of cost that doesn't bring value to the people we serve, either as insurance company members or as patients. And essentially to prove that some of that value can be a robust business model, some of it basically

has to be given back to the folks who are either buying our insurance product or the folks that are getting our services. Some of it's obviously going back to the public payer very quickly but some of it can be redistributed within our unusual fiduciary with both payer and provider in a way that allows us to do about 30 to 40 percent of our business in a fundamentally innovative way.

So I'm just, I'm trying to describe to you this kind of perfect experimental venue and then our commitment. So the issue then is with all the data on the claim side, with all the data on the electronic health record side, for 20 to 30 years with a data warehouse that is actually now in its third generation so it's about 12 years' worth of looking at our own analytics. With new information about proteomics and genomics kind of added on to our clinical commitment to redesign care, what is it we can do? What is it we're really focused on? And the question is how do you analyze those data? How do you create cohorts of usable information to change behavior?

We think that most of our attack on this 30 to 40 percent of stuff that's done that doesn't help human beings or that actually can hurt them, can only be transacted by a fundamental change in behavior, taking the big data and taking the analytics that are available through these huge accumulations of data and creating appropriate, immediately usable packages that can enable a change in how an individual who's providing care provides that care to a patient sitting in front of him or her, or how you can actually connect the analytics, what have you, with the change in behavior of a member of the insurance company or a change of behavior of a patient quite apart from their interaction with the provider. And, you know, we have, we've gotten a reasonable amount of celebration in terms of our hospital associated re-engineering and have felt progressively more confident over the last 10 years that most of the re-engineering that we've done actually is both a help in terms of quality outcome as well as decreasing costs.

We think, we think that this is in fact an enabled by real time data feedback by modification of how that data comes back, and we can talk about that in discussion, so that it's immediately usable. We think that the ability to activate human beings, whether they're insurance company members or whether they're our patients is the next major aspiration. One small step that we might discuss in more detail is the opening up of our progress notes –

Ralph Muller: I want to follow up on one of the structural differences between partners and Geisinger around the insurance function. As before the kind of exposure they gave in the last 10 years that brought you here today and you heard about in the previous panel. Most of us really relied on administrative data or insurance data into Forrest Medicare as a big

insurance company. And now we have a lot of other rich data. As Glenn just said part of what Geisinger has by having both insurance function and a patient care function it's able to take those two data sources and try to bring them together. And the prototypes for all of this has been Kaiser over the years going back 60-70 years by having the physician function, the production function of a hospital, the insurance function and so forth. So I'd like, let me ask Gary first, do you feel that that kind of insurance data, payment data in a world of "affordable care" where would people tired of being together how you pay for it and how you deliver it? Is that something you need as well to better deliver care to your patients and then maybe Glenn can come back on that as well. Not that I'm asking, I know you have some modest insurance function there but to what extent do you need that kind of data as well to better improve patient care. Not only the rich data that you have and that you described a few minutes ago but also does that kind of payment data need to be available to you as well?

Gary Gottlieb: So as you pointed out we acquired a health plan just a year ago and which has been largely working in Medicaid as well as in subsidized. In the subsidized products that were on the exchange in Massachusetts and also did well on the commercial side in the exchange Howitt will do in the next iteration but clearly we want to expand some activities. The data are not all on the same patients. I mean we share probably of the 250,000 of their lives probably 80,000 of them are who get care in partners and that will certainly form various aspects in that sub segment but it's only a very small amount of our business. However, I do believe that there are substantial skills and competencies that the insurance side has created particularly over managing high risk and poor populations as well as some duly eligible populations that we can learn from substantially. Whether we'll be able to use data as well as Glenn is describing is a different question. I guess what we have felt in our relationship with the insurance companies is that claims and administrative data tell a narrow segment of the story to be able to have the flesh of those patients from both perspectives from a highly personal level a very detailed level. The observations that are now frankly being shared with the patients themselves and the way that you're describing progress notes and to have administrative data as well really can increase the value of the administrative data and make it predictive in a variety of ways. Probably creating efficiencies that we don't yet have. What we're getting from both Medicare and from the insurance companies with which we have risk other than the one that we own, are often delayed. There's always at least a several month latency that makes managing interesting problems much more difficult. At least doing secondary intrusionary prevention more difficult which is where much of the cost is and being appropriately empathic to the prior panels point of view more difficult. And I don't think that necessarily having both creates the excellence and the value that

Geisinger has. Geisinger has been deliberate, thoughtful, strategic and is married in having that knowledge together with a driving curiosity to improve because there are many others who have insurance functions who haven't used them quite as well.

Glenn D Steele Jr: Now we're different than KP. We are much more heterogeneous then Kaiser. I say 50 percent of the care that is given to our insurance company members is given by non- Geisinger, non-employed. Now that's not a randomized control group obviously but when we're looking at trying to apply something we can look at our own group which is obviously enabled by our data capacities versus non- Geisinger, non-employed. And they have a variety of data capacities. We also can look at differences in incentives, since obviously our employees group we have more leverage in how we pay and essentially and what we incent for. But we also have as opposed to Kaiser we also have a huge number of our platforms. We now have eight hospital platforms. A significant number of them are dependent upon non-employed, non-Geisinger taking care of their patients in their patients in those platforms. So you know the difficult thing in terms of the administration is that they are not all in that sweet spot. The interesting thing about that is that it's more like the real world. So if we find that we've done an innovation in our hospital based care or in our taking care of patients with multiple chronic diseases we start with a sweet spot of our own employed and our own insured and then we can say does this work much more typical, much more heterogeneous market. And that's kind of interesting. That's our first test about whether a lot of this observational stuff that we do really has legs and again it's not like an RCT but it's more like a business model of reproducibility. So again we're a little bit different than KP. But we think the fundamental capacities of an insurance company in terms of data are different then the fundamental capacities of a provider group and data. And it's not just assuming risk, it's not just hedging risk it's not just avoiding risk which is the usual kind of clinical character of the insurance company. It's more than that. We also think that because we have both the insurance data and the clinical data within the same fiduciary we can at least theoretically have the leaders of those two data sets working together to the benefit of the people that we actually serve. Now that sounds kind of smarmy to most of you but trust me 40 percent of our payer or 50 percent of our payer is non-Geisinger payer and our relationship with those payers although respectful is the usual relationship where you want us in your network here's what you're going to pay us. So it's a completely different discussion then the insurance provider in Geisinger and the clinical provider in Geisinger saying let's look at type II diabetics 30,000 and let's see if we can get a better result in terms of retinopathy or neuropathy or myocardial infarction incidents and stroke and how do we do that. How do we enable the data flow so that's immediately useable either by our endocrinologists or our

endocrinologists and our PCP's working together? How do we look at near term metrics to make sure we're not screwing up and then how do we incent for it. Usually the question of how to incent for it comes after is it a worthy target. And how do we set up the metrics and how do we get the information flow back and forth so that it's usable. So again my belief is that if our model can be scaled it really is framed by a fundamentally different kind of vertical integration than anything we've seen before between payer and provider. And by the way it doesn't happen with CMS. Tremendous worthy well intentioned folks that we worked with during PGP, physician group demonstration project but the data that came to us when they were doing the experiment which was the precedent I think for ACO's came to us 6 months, 12 months, 18 months after the fact. That's not useable, that's not useable. So I think the kinetics of this is also very important.

Gary Gottlieb: Another element, not just the latency of the data but the form in which the data are collected. So the overall platform that collect those administrative data are used to pay claims and it is very expensive to reprogram claims payment structures and claims payment programs for insurance companies. So as one starts to move to more creative payment approaches, bundle payments in particular most insurance companies are loathed to really participate in something that they might in fact find very beneficial for the patient populations that would derive the kind of analysis you describe by conditions by specific episodes of care, by managing the population because it is just so expensive and difficult to reformat their claims payment mechanism and also a lot of their claims payments sit in one sector. They didn't sit in home services and there are lots things that are excluded for payment. So if they're excluded for payment there're ideas and potential costs that aren't captured and the incentive isn't there to capture them where as you have that in collective. So if you know you're going to do telephone visits or be able to respond to data in real time you can make that something that's actually paid for as you work on those experiments.

Ralph Muller: And one of the things both of you do as CEO is have to make major decisions about strategy and allocation of resources and I know in recent months and days you both announced big expansions of your systems. Now my experience in the past has been when I think about how to improve patient care without getting without getting too much stereotypical about this if I ask a nurse how to improve patient care, give me more nurses and get more masses prepared nurses. And I've asked somebody in IT how do you improve patient care they want an EHR and so forth. So by and large we are all kind of prisoners of how we look at the world. How do you think about investments and big data? I mean obviously in your jobs your thinking about how many nurses, how many

hospitals to buy, whether you have an insurance company or how much you invest in genomics. How do you think about this in general? Is this basically one does budgeting at a macro federal level. You take whatever you have right now and you add a little bit to it but are there broader ways of thinking about what you're willing to invest in this kind of explosion of information.

Glenn D Steele Jr: Well first of all we have a rule at Geisinger for any aspiring leaders. And if they come to me and their answer to a problem is more it's the end of their trajectory at Geisinger *[Laughter]*. It's one of those things I can get away with that I couldn't when I was an academic.

Gary Gottlieb: Working in a--

Ralph Muller: We don't have that answer.

Glenn D Steele Jr: That's really dull.

Gary Gottlieb: --Right working in a place with two academic medalists if they don't ask for more the trajectory goes in the wrong direction.

Glenn D Steele Jr: Right. Right. But I think there are some things that we take credit for that we shouldn't actually get credit for so when I came there I mean a part from the dysfunctional three and a half year merger that had just been transacted and then taken apart and the chaos in the various operating units, apart from that we were in great shape with a decision back in 1995 which I think is quite rational on the one hand to become electronic. I mean at that time we had like 78 site spread over 41 or 42 very rural or postindustrial parts of Pennsylvania and we couldn't have functioned as a system without electronic health record. Now though the wise part of the decision or the lucky part of the decision that we happen to partner with a vendor who turned out to be extraordinarily creative and end up with a huge market share, Epic. And we've had 20 years of modification of Epic and trust me it's the modification of, it's the boltons that make this thing functional plus the fact that almost everything we do when we're looking at how data actually works to the benefit of a change in process is built into a commitment to change the entire human process. I mean what we've found over and over again is that if you just add an electronic interface without fundamentally looking at reengineering your process you can really screw things up. You can really make things worse. And

there's a lot of literature to that effect as well. So you know I inherited this, I mean I inherited the Children's Hospital in the area of a country that had one of the lowest birth rates in the world. So I had to figure out how to make it work. And again, Ralph, once we did a lot of the fundamental things to get over the three and a half year strategic blunder we basically said what is it that we could that really great people in great institutions, like Penn, like Chicago, like Partners probably would have more difficulty doing. And again that was looking at our demography, looking at our payer and provider vertical integration, looking at our market share and saying I think we can ask questions about having all of these stakeholders participate in extracting a lot of that 30 percent of costs. Now how do we do that I mean without having real data feedback. And in a way we kind of had a control. It was a randomized control but we had PGP where there wasn't real time data feedback. We had real time data feedback from our Medicare advantage, Medicare HMO and on the one hand we got great results in terms, and a sustainable business model even with the revenue having been traded over the last few years and on the other hand we got great results in terms of quality and we got screwed by the government. So I mean no it was an interesting – so I'm pretty much committed to keeping our electronic record and our data warehousing capability at the aggressive end of the benchmark. We're spending about 4.6 percent of our revenue each year on our EHR and I'm doing that as initially I did it as a matter of faith. I now have actual ROI presumably as much whole cost based ROI on a number of things that Gary was eluding to. Particularly the patients with four or five chronic diseases. And it took us about 15 years at Geisinger before we started to get a return on that investment if you include the initial down stroke and the trajectory of that return on investment over the last five or six years has increased. The slope has increased year over year. And I'm hoping that other people can learn in a much more efficient way than we learned in the first 15 years of our existence. But it took a long time before we got that ROI.

Gary Gottlieb: So I told our finance committee that we could learn from the last five years of what you've been doing at this slope and that if we had 15 year ROI it would be not a justification. Exactly. It would be faster than asking you for more nursing staff on a given unit. We've had a very long and traditional investment in IT really as a tool for safety. Some of the work that Troy was talking about, that David Bates and others led going back to the implementation of some of the first locally developed computerized physician order entry systems, decision support, our on electronic health record. Also with decision support our own barcoding electronic medication administration record was at a time it was unclear whether we were health care delivery organization or an IT shop but there was not a lot of capital in healthcare IT except for EPIC and a few others who were in a variety of different places and the focus in Partners and the focus

over the first decade of the century was on safety and really trying to take what we had learned from those early implementations and make certain that every part of the system had a level of error reduction over all. That created frankly a patchwork quilt of different systems and to some extent heterogeneity of data that could not inform us strategically and that would not allow us to invest and frankly we discovered that we couldn't invest enough capital to be able to keep up with the kind of technology advancements we believed to have been necessary to improve care to improve safety and to improve data and knowledge. And so basically across that very large system I just described. The two very large academic medical centers, a number of community hospitals, rehab, psych hospital and community network, we're ripping out our existing systems and we're implementing Epic across the system with the focus on a number of elements of workflow redesign that are by far the most expensive piece of this implementation over a period of time. Now the question to some extent is how much of that is an investment in big data and how much of that is in improving care. Being able to consistently improve care at the bedside and in the office to be able to improve the flow of information which becomes big data whether it's transactional among providers but for us we see it as critical to being able to provide the best possible care and to be able to support the various business functions that we're all talking about going forward. The second part of the question is though is then how much do you spend on warehousing those data, on analytics which are both not just software tools but the number of analysts who work in and throughout the system how much a part of the system becomes overhead that's dedicated to thinking about yourself, analyzing yourself and informing yourself. And that's something I think that we really don't understand the balance and our parsimony becomes really driven by our budget and the downward pressure on unit costs. And to some extent we cut off our nose to spite our face around things that might have a longer term solution related to a broader vision of what we're trying to accomplish with this very big investment.

Ralph Muller: I'm going to ask one more question directly of them and then so within five minutes I'll invite members of the audience to come up. You know part of what you also do as CEO's is you kind of see signals from society whether it's expressed through affordable care acts or from insurers or from publics at large, is to think about what kind of competencies does an organization whether it's Partners or Geisinger need especially with this advent of big data. And we've obviously heard a lot of it in the last 10 years in so of bringing bioinformatics into our kind of places and Glenn has done a very good job really describing some of the competencies that Geisinger developed but as you think about big data our topic today. What kind of competencies do big organization such as Geisinger and Partners and by extension others like that inside this room, what kind of competencies does the organization as a whole need to develop?

Glenn D Steele Jr: Well I think that the answer falls into two categories. There are very important areas of expertise that really focus on the transaction and then continuing upgrading of the transaction as it now is and as we expand and we go into particularly a number of platforms that haven't had a lot of capital for a period of time and they have been under invested in. And we have to more or less Geisinger them. I mean that takes an incredible amount of talent patience, competence and it's not just the technical competence, it's changing the sociology. I mean trust me going into Scranton with Epic that's an interesting Sociological issue and it works but it takes certain competence. There's a second category though that is more important to me as the head of the organization and I'm sure for Gary as well. I would love 15 years or 20 years from now to have someone look back and say, "You know there were two or three seminal decisions made that got us as an organization ahead of the curve, similar to the decision in 1995 to go electronic with an ambulatory. And obviously I don't know what those seminal, what those transformative projects should be but what I'm kind of doing and it's just part of my personality. I'm trying to look outside. Of health care to a large extent. To bring in people at a certain level in our information technology and information services in both the well actually in three compartments. One is on the insurance side, one is on the clinical enterprise side and one is on this side of the company that we've started is trying to take our intellectual property outside of our markets. And I'm looking to ask how do we emancipate ourselves from pipe. I mean so much of what we're doing now is just connected to pipe. For good reason and bad. For good reason we get security and confidentiality issues. The bad reason we need to be emancipated from pipe is because of the propriety design nature of so much of the pipe. It's very, very difficult to get these things interoperable. It's very difficult to change them easily and what have you. In almost all other areas where data has been used throughout an industry for as long as we've been using it we've got distributed data. You've got data that can be activated and changed and what have you. So I'd like to have a central repository where we can actually look at patterns and where we can actually make decisions about how to package data that's useable but I'd really love to see much more distributed data. And that's going to mean a much more activation of human beings in ways that have happened in other industries for quite a while. Now that's going to mean that the folks that we're serving out there, I mean they've got to come to a different balance in usability of data versus security and confidentiality. Now at least in my family and I now have four generations in my family there's a distinct difference in terms of that balance between usability and security and confidentiality as you go from one generation to another and so I'm trying to get the expertise and I'm actually recruiting people from outside of healthcare to help me with that.

Gary Gottlieb: I guess the most important competence we need is humility because of just the depth of change that we're embracing and just the willingness to be flexible by being informed with these data to start with so one to understand that in management one has to make some pretty clear decisions about how the data are governed, what data are to be included in the data repositories one's is describing, how they are to be cared for and to be certain that they are protected in the way it's described but also that they are in fact reflective of the truth. And what they were intended to be as they're being processed. Second is a degree of willingness and expertise as to how to truly be dependent on an evidence base. We say that we do work that's evidence based but now you're talking about transactions and decisions in real time that need to be derived from evidence about that individual patient or about a broader set of evidence that are available and while I think that most clinicians and physicians are trained around the notion of decision making under conditions of uncertainty we don't really know how to measure the probabilities that are associated with the data that are being given to us. And then for from a teaching perspective we need a set of competencies as how to use those data in making finite transactional decisions as well as broader management decisions and that I think is relatively new to us. You know each of us has embraced engineering and reengineering as saying the way that we were delivering healthcare before needed to be reengineered and therefore we'll adapt a simplistic approach to looking at work flow redesign and many of us have embrace lean and other approaches. That's without any of us being students of engineering. Without any of us being students of a broad evidence based but it's seemed that something worked that our colleagues were able to make work therefore we could adapt it. Now we're not going to be able to generalize in that way to broad swaps of changing the way that we do this work and we're going to need a lot of help to be able to do it.

Ralph Muller: All right. We'll now invite questions. Please just introduce yourself and ask your question. Thank you.

Caroline Poplin: I'm Doctor Caroline Poplin, I'm a general internist. You're sort of at the theory 2000 foot level and I'm down on the ground in the exam room. And I'm troubled by the EHR's that I've seen and I've seen quite a few because I also work for social security reviewing disability applications. It has to do with the formats that we're given. They don't let me put in the information that I need. When I'm dealing with a patient, particularly with diagnosis which is a much more difficult area to deal with than treatment. Once you know what the diagnosis is then you can look up the treatment. It's very important what the patient said and how they said it because it's

not just this one time that you want to know what the patient said. A year from now you know if what the patient is talking about is the same thing or something different. And when I get a note from some other doctor I want to know what the patient said. And what the doctor thought. Not just a list of symptoms off a checklist, assessment and plan, this medication for this many days. I don't want a list of problems that says, "CAD Coronary Artery Disease." Well did he have an MI? Did he have a CAVAGE? Is this just something from an EBCT? A test that he's had or he has hyper cholesterol lemma. And all of this information is left out. And I just get kind of basic outline and that may so that all the data will work in the big data system. And I worry a little bit. Number one it's hard for me. I mean it's better than nothing. And I also worry about garbage in, garbage out. If you're missing the most important things then what you put together, how valid is it.

Glenn D Steele Jr: Yeah. I mean I was a doctor too before I was a suit. *[Laughter]* and I seem to recall that there was a lot of garbage in garbage out with paper records and we couldn't even tell because they weren't inaccessible at least we can tell when there's garbage in garbage out with electronics stuff. And obviously if you've got a template electronic health record that doesn't allow you to be a doctor it's not going to help. It's not going to help. So I mean I agree with you. It can't restrict you but it certainly is no different than paper records. I mean there was a lot of garbage in garbage out.

Gary Gottlieb: That's for certain. One of the questions is virtually in all electronic health records except for the most reductionist there's space for free text and pretty unlimited free text. Once that becomes part of somebody's chart it becomes as hard to query as a giant chart that somebody who has been in the emergency room a million times. And while there are now some tools that we and others have evolved to be able to search those efficiently and effectively the question is are we creating giant masses of unsearchable data for each patient and believing because we're sharing a record that somehow we've communicated effectively. And that can't be the case either.

Caroline Poplin: That's true but is it more important for to collect data or for me to take care of the patient.

Glenn D Steele Jr: No. No. No. That's a complete false para. That's a completely false statement.

Gary Gottlieb: There should be a ton of free text that is in there.

Glenn D Steele Jr: If we're basically focused on having our practitioners particularly our community practitioner take care of 25,000 patients and have a fundamentally different way of approaching Type II diabetes they're not going to be able to do it without data feedback and it is all about taking care of patients better. Trust me. Trust me.

Ralph Muller: Next question please.

Mark Berger: Mark Berger Pfizer Real World Data and Analytics. I just want to come back to the point that you and this panel have talked about and the last panel as well which has to do with the use of observational data to inform health policy decisions and as all the data gets digitized and we end up with unlimited data capture we have an oceanic sea of observational data which can now be analyzed by traditional analytic methods or by advanced analytic methods. And we've heard of examples where those results are misleading. No big surprise. And we've heard of examples where they say big data has done something and they come up with the wrong answer. Some of us have argued that in order to make policy recommendations you need to have replicability of data so that you should not just do it once in one population but show it's reproducible in multiple different populations before you make a policy recommendation. The alternative way to go is what they do in big data companies which is disciplined experimentation. They come up with a thing and then they can show within days or minutes or nano seconds that they're algorithm actually works. We don't have that luxury in medicine. When we put and algorithm in place it takes us a lot longer to figure out whether that algorithm has worked. It's been my experience that in the peer review literature we have some sort of idea about people looking at the quality of what we do and I've worked for a payer in the past. Payers don't actually aren't as transparent about how they're doing their disciplinary experimentation and publishing the results of how they're doing it to show that they're actually splitting the data sample and finding a predictive model in one part of the population and then reproducing it in another before they start applying it with patients. What is the wisdom that we should have because the amount of data is running way ahead of our understanding what are the best methods for deciding when should we use this data, when shouldn't we use this data and what are the strengths and limits of the data.

Ralph Muller: Great question sir. Gary or Glenn do you want to try first.

Glenn D Steele Jr: Yeah well you know I think in fact there is pretty rapid feedback from predictive models. I mean our insurance company essentially just as a fairly glib example of what you're talking about predicts individual cohorts of patients or patients within individual practices and we have 70 practices scattered around that are most apt to need care over a relatively short period of time. And we can tell fairly quickly whether they're right or wrong. Another example is Medicaid Manny's Care experiment. I mean we've just gone into 120,000 member Medicaid Manny's care. And it's a very large revenue stream with no known margin and we're betting on the fact that between us as a payer and us as a provider, we can predict a significant number of particularly the SSI component of that group who we need to focus on and who we need to help dramatically. And you know what if that doesn't work month to month. So I do believe, I believe one of the answers that came up to the question that came up in the first panel and you're question right now is that being able to do the road tests and to do them in a way that is immediately feedback so that the model if it's not right gets changed or you drop the model is absolutely critical. I think there are other answers to your very important concern about methodology for observational data overall. And I'm searching like you for that but I think that the road test thing and the feedback is one thing that we feel really comfortable with.

Mark Berger: Just to quickly comment, when Troy presented his data with an R square .85, that's out of this park. I mean most predictive models have an R squared .2 -.25 at best. So if we actually get to be able to be able to have predictive models to explain 85 percent of the variance I would feel more comfortable about that.

Glenn D Steele Jr: Sure.

Monica Kohler: Good Morning, my name is Monique Kohler and I'm from Biomed Spine and Bone healing. My question for you today is as I listen to discussion about big data, both here today and just in the broader health care community. I see it very much focused on care pathways and pharmacy utilization and that makes tremendous sense and I understand that. I'm wondering though if anyone is talking about device? In particularly a implantable device and looking to the data for any decisions either as providers like a health care system or in the context that you have exposure to being payers.

Gary Gottlieb: Absolutely. I mean looking at devices in particular is extremely compelling. Clearly as we're trying to figure out in many cases what the appropriate algorithm is for the use of devices for surgical rather than rehabilitatable approaches to specific complaints and or syndromes and additionally differentiating among devices. I mean that's one of the beautiful pieces of having a large data repository one can look across brands. One can look at brands and surgeons when you talk about spine and other related devices or in terms of cardiac implantable to look at outcome over a period of time. The effects on function as well as the decisions that led specifically to the use of the device. So I think that it is very, very ripe and it's a ripe area of focus in Medicare. And a Medicare advantage in particular. It's been one that Medicare is trying to make policy around with the bluntest possible sword doing wreck and other related audits to determine that essentially more hospital intervention was not necessary retroactively as it related to a specific device implementation.

Ralph Muller: I would just point out that at all three places, these data stores, we may call them differently are very rich to answer the kinds of questions that I think you suggest. In fact I remember the state going back 15 years or so in the '90s when the Hillary caveats were being proposed and people were thinking about were the insurance companies going to have the most information about patients, were providers, were pharmaceuticals, were device people. And I would say that the rich data that the providers have been able to accumulate with the accumulative effort of the EHR as Glenn described that Geisinger has done for 15 to 20 years and other places because very rich data to look at all that kind of information so one of the viable things that we have and we haven't discussed today what kind of business proposition comes out of it but we have very rich data to analyze an awful lot of questions.

Gary Gottlieb: Also if you kind of take a look at the roadmap of PCORI. I think it will create a structure for these kind of analysis.

Glenn D Steele Jr: Yeah. And I'm not sure if this speaks to your question now but one of the interesting things about the business models of device companies is that those business models are going to fundamentally change over the next five to ten years. And the people who are making the decisions to buy those devices now are usually pretty compartmentalized. And it's all about price per unit or it's about cost per unit. And what we're probably going to evolve towards over a relatively short period of time is what does that device do over some period of time. In terms of the entire cost of care. And as we move from, for instance from culture diagnosis of most infections to molecular. The buy decision has to be looked at in terms of

how many patients with infections are not brought on to the med-surg floors for instance. And how quickly can that diagnosis occur with how much fewer personnel in a laboratory. And so the cost decision if it's left just to the pathology laboratory is probably going to be inappropriate and that PNL has to be widened out. So the whole device I think business model is going to be a big part of the health care change over the next few years. Very interesting.

Monica Kohler: Thank you.

Tom Lou: Hi my name is Tom Lou and I'm with the Advisement Board Committee. First of all thank you so much for sharing your thoughts with us this morning. I have a question for using big data for population health and specifically identifying those patients who are most at risk of avoidable or unnecessary utilization say over the next year as Dr. Steele you described. And my question is how much of a patients risk do you think you can capture using a combination of clinical data and payer claims data. And then what aspects of a patients risk do you think that doesn't capture and what are some ways you guys are thinking of getting a fuller picture of a patients risk?

Glenn D Steele Jr: Yeah well we capture a huge amount and our starting point, our starting point is so bad and we're trying to create a delta and if we can show a 7 to 8 percent delta over a few years just by looking at pretty simple stuff and the simplest is whatever cohort in a practice with the highest utilizing cohort last year is going to be the highest utilizing cohort this year. I mean it's pretty straight forward so I mean you got to focus on them. You got to focus on them. I think for the Medicaid managed care we've been able to focus on kids and a cohort that have chronic disease particularly chronic disease aggregates or developmental issues and I think it's pretty straight forward. Now if you're trying to move beyond that I think we have the ability now to capture a lot of information even in the folks that are not in that highest utilizing group by getting information in without patients necessarily having to see their physicians or their nurse practitioners or having to go to the hospital platform and that looks at weight. It looks at blood pressure. It can look at a lot of data that comes in that can then be utilized to then trip off an action and that's in play right now. That's happening.

Gary Gottlieb: Not to be too provable with my own personal specialty. I can tell you that both claims data and electronic health data severely under capture observation of behavioral disorders. Particularly primary psychiatrist

diagnosis including depression and psychosis. As well as substance use in both illicit substances and prescription drugs. Both of which we find in virtually every cohort of our own employees and our self-insured 80 some odd thousands of us in Medicare risk work that we do. In the Medicaid risk as well as in commercial populations. That two out of the five most important diagnosis are in our high users and there are two different diagnosis in all of them, in each of them depending upon the subcategory that explain the overall variance relate to specific brain disease and or substance abuse disorder. And one having gutted the system overall over the last 20 years as well as having created rules that have diminished access make the measurement non-routine and frankly create biased data sets because many of the data repositories that are used are based upon long histories with car bats or others barriers to access in terms of utilization and therefore they severely under collect data that would predict utilization if you were at full risk.

Glenn D Steele Jr: Now let me just emphasis that not only is it bad data on the claims side for behavior but as Gary said quickly there in most markets it's carved out. It's carved out so that it can be managed by the public payer in a much more robust manner. But everybody knows that the interface between behavioral and problems and other problems is absolutely obvious. So it should not be carved out.

Jared Stalls: Jared Stalls Spectrum Health Hospitals, I'm a Senior Informatics analyst. Our organizations have been on the out-patient setting for Epic for about four years now and it's my assumption that we'll also be adapting the inpatient as well to become sort of that one-stop shop for Epic. What's your opinion on sort of the monolithic strategy versus the best of breed type systems in terms of integrating data. What are the pros and cons? I've seen with like monolithic systems you may have sort of a specialty that has an A in one area and maybe a D in one area. Whereas the best of breed you may have more issues of integration or getting that data into a centralized data repository.

Gary Gottlieb: So we're on the hoping end that the monolithic approach will work because we've had a number of best of breed applications some of which that Epic is designing in its next reiteration to be able to be immutable that we're substituting for. I can tell you when you take those away from people or try to modify them it's not embraced with great joy. It's a test of leadership and growth *[Laughter]*. Actually it is the question of the definition of empathy and trying to find accurate empathy. At the same time it is tremendously inefficient in being able to follow a population and being able to integrate data. The expense of interfaces is remarkable. No matter what anybody says about essentially interoperability being a

solution. It is very expensive. It is extremely challenging. And it's a waste of programmer time or redesign time. At least it has been in many of our uses. So it has driven us to try to move to an enterprise wide solution.

Glenn D Steele Jr: We also have opted from monolithic and I just want to add one thing to what Gary said. I think the sociology of an organization is extraordinarily important if you're going to get that done. And our organization for 100 years has had an unusual sociology where it actually has concern for others and is willing to look at what would be a good commonality even if it's somewhat of a compromise for a specific area. And you can't take that for granted and there are different and I'm not making an value judgment it's just very different from some of the other venues that I've been to. So we've opted for monolithic but it does have huge issues.

Lee Fleisher: Lee Fleisher from Pennshare of Anesthesiology. So I know what we do at Penn as far as data stores and analytics and Glenn you mentioned a percent devoted to analytics. So my question is how do you actually govern analytics separate from creating dashboards because dashboards we're all creating but when an individual wants to or a group comes together and say we'd like to answer this question. How do you prioritize, how do you actually get the diversity of individuals together to ask the right question. Because in fact in my mind in all the years that I've been doing this the right question takes the longest part and with the new analysis systems that's the short part.

Glenn D Steele Jr: Again we have an advantage because we're pretty focused on fundamental change in the episodes of care and trying to monitor that with near term and long term cost and quality metrics that can be agreed upon so that's the solution that everything basically has to – that's the end point that everything has to solve to. Now what we've done is we've created outside of our operational units particularly as we've gotten large and complex we've created innovation and transformation units and those units do not have operational duties. They're not running an anesthesia PNL they're not a service line what have you. They obviously have a budget and what have you but their tasked with the service line leaders to set the priorities and we prioritize the goals and the expenditures in a way just like we prioritize capital. So there is a way to do that. Our advantage is we're not doing a huge amount of mammalian genetics. We're not doing a huge amount of other stuff that you probably are and it may be taking up a significant amount of that analytic time.

Gary Gottlieb: You're asking the I think very powerful question of balancing what are the elements of the culture that you're in that have defined the place, have defined the people and have created extraordinary assets because of a lack of hierarchy in some of the decision making that you've described. Penn is among those magnificent institutions in the world which has attracted exceptional people who have been able to be entrepreneurs and have been able to pursue hypothesis testing and or projects and solutions in innovations in a very broad base of areas with what have felt like unlimited resources. And in a challenging environment that becomes more targeted. How does one balance still being able to nurture that sense of innovation and creativity and at the same time start to focus on a pseudo-efficiency where there's a significant limitation of resources and where as it comes to this there really has to be a prioritization. And I think that that's a struggle for all of us as we try to transform academic institutions that have broad multifaceted admissions and I think that ultimately it's the availability of resources that will guide us and that give us an extra tool to be able to manage them with a higher degree of discipline. But at the same time constantly focusing on that multifaceted admission because if we lose our way in that regard than we will not essentially be able to charge a premium either in the sole of society or from a price perspective for the extra stuff that we do that doesn't demonstrate the significant ROI value that's more immediately available in a more efficiently managed environment.

Ralph Muller: Okay. Last question now.

Audience Member: I wanted to congratulate Jeff on bringing these great institutions together. But all of you as great institutions have a limited number of people in the population how do you share results of hypotheses. Particularly if we're looking at disease hypotheses and cause and effect among the institutions. I'm told that until we can get to a population of 55 million patients in a data base. We can't really extract significant cohorts to make some decisions. So my questions is so how are you sharing and since infrastructure's an issue what are you looking at in terms of infrastructure to share with other great institutions like yourselves?

Gary Gottlieb: So one of the major premises that the NIH put forward with CTSA's was to start to create the kind of data repository that you described and one of the projects that actually was derived out of what we were able to bring from the research patient data repository that I described and similar data repositories from others is a project called Shrine that will begin to create a similar set of phenotypic data across a large number of CTSA's which are basically the survivors of GCRC's but in a smaller number but with very large patient populations across the country. Now how long it takes

to evolve that is unclear but it will theoretically create a pretty disciplined and highly correlated set of variables to be able to start to look at some of the data that you described and additionally through the other project that I described of natural language processing bring real time clinical chart data and to be able to enhance that data set. That's somewhat of a dream. I think it's a multiyear dream but it's certainly part of the vision that the NIH is trying to put together with that.

Glenn D Steele Jr: Yeah I think there are a couple of answers to your question for us. Number one there's just a huge amount of consolidating that's going on the provider side of the market so I predict that over a number of years we're going to have fewer, larger provider aggregations so there will be even within a given fiduciary a reason to share. The second answer is partnering. We're doing a huge amount of partnering with Biopharma, with technology companies and what have you in order to try and garner the resources and garner their distribution channels to learn as well as to teach and I think the final thing which is more of a fantasy than anything else is, I mean I'm convinced and we're recruiting people who know a hell a lot more than I know about the actual technology that a fundamental problem with what we're dealing with now is the design principle of electronic health record and that if we were able to do some sort of an open source approach and just blow the pipe right out of the universe that would be kind of cool because it's happened in many, many other industries as we know. And I'm just not convinced that the confidentiality security issues, which are real are going to technically rate limiting in another few years.

Ralph Muller: I want to thank. I think you can see from the breadth and depth of the comments from Glenn and Gary why they are individually so successful and why Partners and Geisinger do so well. I suppose I should end as Jeff did with some sports information. So you may have heard the breaking news that the Washington Redskins are changing their name. They're dropping the name Washington because it's too embarrassing.

Glenn D Steele Jr: That's good Gary. It's always good to share a podium with you yeah. Great.

Jeffrey C Lerner: Okay. That was a brilliant panel. I truly was. So listen we're coming up on lunch in about one minute but I have to urge you to please be really attentive to the time because we're going to start the next session really on the button at 1:00 pm and here's why that's a challenge. There are four speakers in the next session on EHR's that's a lot of people. The

amount of information is going to be extraordinary. So they have a tough challenge. Really very hard so again I thank you all and we'll reconvene in one hour. Thank you.

SESSION 3: THE MOST ADVANCED EHRS

Electronic Health Records (EHRs) were designed primarily to address reimbursement and care coordination issues. But efforts are under way to help improve and guide care delivery, carry out research, and inform quality assessment. How are providers using EHRs to manage their networks and determine how to deliver the best care to patients? This session examines the progress towards making EHRs the linchpin of big data in provider and payer settings.

Moderator: **Lee A. Fleisher, M.D.,** Chair, Department of Anesthesiology and Critical Care, University of Pennsylvania Health System

Steve G. Peters, M.D., Vice Chief Medical Information Officer, Mayo Clinic

Theresa Cullen, M.D., M.S., Director, Health Informatics, Veterans Health Administration

Terhilda Garrido, M.P.H., Vice President, Health Information Technology Transformation & Analytics, Kaiser Permanente

Jan Lee, M.D., Executive Director, Delaware Health Information Network (DHIN)

Steve Peters: Thank you. Thanks for having me. I've enjoyed the conference so far. So, let me give you a whirlwind tour of the Mayo Clinic and what we're

doing in the electronic health record environment. We have three major facilities: the original home of the Mayo Clinic in Rochester, Minnesota, and then institutions with hospital and clinic complexes in Jacksonville, Florida, and in Scottsdale and Phoenix, Arizona, that have been in place about 25 years.

We have a regional health system that's fully owned and operated by Mayo Clinic, and then an expanding affiliated care network. Our C-suite has told us they're really not interested in brick-and-mortar or more physical expansion, but rather would like to treat Mayo Clinic knowledge as a scalable asset and reach out with tools for these affiliates that include access to a tool I'll show you briefly called Ask Mayo Expert that has knowledge content, but also links to reach Mayo Clinic experts on specific topics and things like e-consults. We're especially looking at payment models that – where the face-to-face consult may not be needed or may not be paid, where sharing information might be of value. We have about 60,000 employees, and 100,000 hospital admissions.

Important to what I'm gonna show, in terms of interoperability, are how the EMRs work. We have, in our Arizona and Florida sites, one version of Cerner. We have a different instance of Cerner in our health system, and we have a Legacy system of GE Centricity Enterprise in Rochester that evolved with best-of-breed modules on top. So, I'll mention a couple of those as we go along.

So, here's a current map that shows the Mayo Clinic sites, and then the expanding, affiliated-care network, which now extends into Mexico and Puerto Rico. So, we have a real need to exchange information.

Briefly, I'll acknowledge and touch on some of these trends. So, we're pushed by meaningful use that hasn't been discussed much yet today. The idea of the quality reporting from PQR or value-based purchasing is heading more towards a convergence, where we picture that outcomes and costs will be more or less streaming from the electronic record to CMS and others, and how we'll accommodate that.

Our users like custom views to support their workflow. I'll show you some examples. Ongoing work in decision support and absolute desire and demand by our clinicians to be mobile. Increasing trend towards patient engagement we've heard some about. Also, care coordination, medical home, accountable care models, and then population management, some of the need for analytics. And big data is the subject.

Because we have different modules, we've developed an overarching, interoperability viewer. This is just one screenshot showing a summary view. The importance – it

looks like any other EMR. The importance here is it's bringing in data from an ICU system, which is a Pices Chart, plus an emergency department system or other medications administered elsewhere in procedural areas. I'm dismayed to show the little fishbone diagram in the bottom right that Dr. Norton commented on. I also don't like it, but that's there, despite my objection that – we go to great lengths to show labs with units with normal ranges, and they make these diagrams where it's hard to know what you're looking at.

Again, our users have identified other needs. And this is a system that our ICU colleagues developed. It's been received well enough that they have a large CMS grant to diffuse this outside of our intensive care units at Mayo. And the idea is that the patients that are complex benefit from an organ system view.

So, in this case, in the upper left, we're showing the – the problem is not a billing problem list, as was alluded to earlier, with CAD NOS. I'll put that down if I'm doing a 15-minute follow-up, because that's all I need to do to justify that bill. That's not a problem. These are the number diagnoses in the clinical note of the attending physician. So, those are extracted and used as the problem list.

So, this patient is in septic shock. The cardiac system is highlighted. I can see the mean arterial pressure is low. I can see if they're on pressors. I can see that an echo was done recently, and I can see that the lactate is out of range. So, at a glance, without – and all these can be drilled. Additionally, one gets a nice view. So, we have been under a fair amount of pressure to keep developing custom bolt-ons that fit the practice.

This is an example of a data mart we heard about earlier, multiple databases coming together to a repository that then can be used to run rules and send reports, be used for education, but also do simple things, like in the case of a sepsis sniffer that we have, a critical care fellow is a sepsis response team. So, separate from a rapid response team, we alert – automatically alert a fellow to go look at certain patients out in the hospital floors.

We do decision support. This is just one example of a trendy version, using pharmacogenomics. So, I participate in a pharmacogenomics task force. We get the scientists on one hand the clinicians on the other and decide what we'll put into the workflow. Is it just some passive education, or in this case, for the drug Abacavir, an HIV drug, where we feel that the adverse reaction, if you have this HLA allele is significant. So, we stop and suggest that before initiating that drug, you may consider doing this gene test.

I mentioned before the Ask Mayo Expert, which is our own home-developed knowledge management system, and here's a link that's on that same screen. It'll be a contextual link to education about this drug and why – what's the rationale. And you can see the tab there also Expert Directory. So, if you'd like to page someone and ask them, or send them an e-mail, you can do that right off this screen. So, some nice contextual links to share information.

So, and example of a passive alert. I'm ordering an MRI scan on someone with renal insufficiency. I don't know what nephrogenic systemic fibrosis is. I probably should. So, we have embedded a link on the order detail screen, telling you there's more to learn about this condition with a gadolinium contrast agent.

We have other management tools. So, this is, again, running off a repository, outside of the core EMR, but used – but navigated right through our synthesis tool I showed you before. It's an example of a patient with diabetes out of control. And the recommended actions I'm showing in the right side of the screen is that the A1C is out of range, the lipids are off, preventative services are due. And these are all – this has become fairly popular for our users because this tool goes out and searches the record and brings this back, the set of guidelines.

Here's an example of a patient with a calculated risk score that's created out of the record, and a very high risk of having – a 45 percent risk of having a heart attack in the next 10 years by Framingham Score. What can we do about that? Well, we can help advise the patient, but here's a shared decision-making tool. And we've heard a lot of these terms this morning, so I'm kind of running through them quickly as highlights and screenshots.

So, in this case, you can offer this to the patient, share the computer. We still have links for the physician, that is in the upper right of the screen, but if you – the patient has heard about the awful side effects of statins, and you can show them that, "In this diagram, you have a 45 percent chance of – 45 people out of 100 will have a heart attack in your condition. If you take the statin, 34 people will still have a heart attack, 55 don't in either case, and 11 people avoided it." So, it's making it graphic, making it simple enough for anyone to understand, and allowing the patient to participate in that decision. And we have a number of these for various conditions.

Another example, chronic disease management, population management. A simple dashboard here that a care coordinator could use, just using hemoglobin A1C as a trigger. The ones on the bottom are okay; the ones in the middle are drifting a bit; and the ones on top should be contacted and come back and have their treatment adjusted.

These, of course, can expand. Patients don't have diabetes alone. They also have hypertension, and they smoke and have other conditions that need to be monitored.

Like many others, we have a patient portal. So, on the left is a tabletop version. On the right is my iPhone. I don't consume a lot of resources. I have no appointments. No appointments found. I'm probably not a good – I get a lot of my care in the coffee room.

Also alluded to earlier includes the access to labs, reports, and notes. So, clinical notes are included real time, and a lot of concern about that and nothing happened really. It may or may not come up for discussion later.

Mobile is highly sought. We started with the devices on the left, what I call the "laptop on a stick." Got dozens of them, then hundreds. Increasingly now, in the center is a real monitor on my kitchen table, and on the right, a pretty good – on my phone – of a patient with cystic fibrosis and a pneumonia with right lower lobe atelectasis. And not for diagnostic resolution, but certainly good for going around and checking on patients.

We heard about all five Vs of big data earlier from Dr. Bo-Linn. And I would stress, then, the value also and the value equation and selling to the C-suite. If you need a few million dollars for a big data appliance, I think it has to show that there's outcome, quality, safety justifies that cost over time, in addition to the other features of big data that we've heard about.

So, why big data? The top part of this is showing there's a lot of information –notes, radiology, pathology reports, and surgical reports – that are semi or unstructured documents, and everyone needs access to this. We did a lot of this manually. For a hundred years, we've indexed the records of Mayo Clinic and used them for epidemiologic and other research, but it's a lot of manual process to codify those diagnoses.

A simple example of outside materials, and Watson and others are beginning to do this. Take a stack, and process it, and come up with – using a variety of techniques, come up with a summary that might indicate the main conditions of that patient. And then the clinician could validate and verify that.

Here's an example of heart failure, showing that there's information across all these systems: problems, notes, echo reports, meds, and the quality reporting. You might want to know how many admissions we had. We have an issue with getting the problem on the problem list, and also making sure the patient gets heart failure education to get to that 95 to 100 percent compliance with core measures. And

researchers want to identify a cohort. Well, these more powerful databases can help us to do this.

When we decide if you need a colonoscopy in three years or ten years, it's a fairly – it seems like a simple decision, but if you parse it out, it's fairly complex. So, you need to know what the patient has had before. What was in the endoscopy notes? Were there polyps? Were they dysplastic? And so on.

This is simply showing a care process of how that's processed in the middle, through a decision support system, and offering the care provider a recommendation. This is also – you're not supposed to be able to see it. How do I decide if a woman with an abnormal cervical pap smear should have additional testing? Well, has there been a hysterectomy? What was the biopsy? Is there carcinoma in situ? Was it dysplasia? Is there a papillomavirus result? This care process is showing that.

And in this case, this is how we would process this. There's a pathology report. Language processing and results have been interpreted, and we're telling this clinician, in this case, "This one is complicated. Refer to colposcopy clinic, 'cause it's likely to need additional testing."

We have shown and use for pretty simple follow-up preventive services that using population management system greatly increases accuracy and compliance. Something like abdominal aneurysm – others have shown this, too – if left to normal clinical screening, it's about 20 or 30 percent, and using decision support tools, it goes to 80 or 90 percent for the recommended follow-up.

We formed a relationship with Optum Labs. It's very exciting for Mayo Clinic. They're bringing a hundred million patients, claims, laboratory values, and demographics. Mayo has data on three to five million people, and a lot of patient-focused research expertise.

Now, we're showing a couple of examples of questions that might be asked. With obesity and other clinical conditions, knee replacements are occurring much younger. How are those outcomes compared to older patients, and what are the implications for redo later? How are newer anticoagulation medications comparing to warfarin that we've used for 40 years? The kidney transplants before dialysis have the better outcome than afterward. So, these are questions that big data can start to touch upon.

And finally, what – we have a complex patient. What are the conditions? We could summarize that. Can the clinician ask, "Have we seen patients like this before? What

were the outcomes?" And for those who had better outcomes, what were the treatments? And we need to do searching across all records. The hundreds and thousands of records is a big data type of problem.

Now, skip over this 'cause we've heard about big data, that it's really bringing the processing to the data rather than a traditional database that we load and analyze in the sake of time.

And the final slide, so we're pretty good in the analytics capabilities in the bottom part of this diagram. We can describe our practice. We can do some queries, a dashboard, and a report. We're just beginning to do this forecasting and predictive modeling and not yet to the type of decision optimization that we'd like to see these tools deliver.

And the summary slide is there. Has a capability to transform, and it's moving us along the path to these predictive and prescriptive analytics. Stop there.

Theresa Cullen: Hi, I'm Terri. How are you guys doing? It's after lunch. I thought that was the bad part of the panel. What I think is that we have so much to share with you, it's going to be amazing.

So, I work at the VA. We're known for big data. Actually, I'm trying to make my slides so they don't interact with other people from the VA that are presenting during this conference. Here's my agenda, but before we start, I want you to take 20 seconds. I think it's three percent of my talk. I know I have 13 minutes. Where is my time? I'm at 12:51. Close your eyes, we're doing mindfulness. Sorry. Seriously, close your eyes, and I want you to think about a dot 30 seconds. I count fast; it'll be less than that. So, just close your eyes and think.

Okay, some of you count faster than me, 'cause you opened your eyes. This is the dot. The dot's the patient. All big data comes from the patient, or from that N of 1, and then of an N of 1,000, N of 10,000, N of 5,000,000. But the nascent Nitus of everything we do in big data is the patient. And while the patient isn't a dot, I've represented them on my slide deck as a dot here.

The patient then becomes the patient and provider, though I would urge you to think of this as more than your typical definition of a provider. It's whoever's in that home, in

that business, in that place of healing that's providing care to this patient. And now we have two.

And then we go patient, family, and provider. And once again, I urge you to think of this not necessarily as the provider. This could be the patient and the hospice homecare team. It could be the patient and your patient aligned care team, which the VA now has 15 percent of our employees in. But whatever, all of a sudden you have a lot more ends. You have a lot more data. You have a lot more difficult way to put this all in a system that may or may not have standards for it.

And then you'd go to a community, and if you could count these dots – I didn't, but somebody did this slide for me – it actually represents a primary care panel. There's supposed to be about 22,000 dots here. So, even though you and I are the ends of one, I as a – I'm still a practicing physician – but I work in ER, but say I was primary care – would have 22,000 of those ends. Difficult to figure out what to do. Difficult to figure out what you need, what's the best for you, what's the best for me, and what's the best for that community of which you're a part. And finally, then you go to a population. And when we talk about big data, it's usually where we end up, these populations.

Now, we may talk about different parts of that population, but what's important to note is that everything in this population has the beginning –, and I would argue, because of the need for bidirectional data – the end of that big dataset. And the reason why health IT and EHRs is so critical, and I know you know this, is because without that N of 1, that that ability to collect that data specific for that patient, you can't do anything with big data 'cause you don't have big data.

I mean we can argue that we do. We can argue we can cull it from the Internet. We can parse. We can go out there and do data mining on other datasets. But for specific things that we need to look at, we really need to have this from a population perspective.

And with that, I'm going to flip you into where we are at the VA right now. So, Vista is our record system. Many of you have heard about it. It's inpatient and outpatient. It's a 35- to 40-year journey. I'm going to finish up my deck at the end, talking about where we're going with Vista. But suffice it to say Vista does a whole lot, and it's been around a long time. And we have a lot of longitudinal historical data, some of which was standardized before there were standards and then translated, some of which continues to not be standardized. And I would argue, in certain domains, that's probably our most critical data, and we can't do big data with it, because we can't figure out how to aggregate it, even if we use things like natural language processing.

Our health care model is a model based on the coordination of care. So, while we care for veterans, we have people coming into our system that may or may not have – that are eligible for care, but may or may not have access to it previously and/or are transitioning from active duty armed services or a public health service. At that point, our job is to care for them for a lifetime. So, while we have people that jump in and out, that seek care otherwise.

Our goal is to create a longitudinal health record from all those datasets that enables us to improve their health status and ensure that, for our perspective, that we achieve health equity for the veteran. If you look at this slide, it should remind you of meaningful use Stage 1, 2, and 3. I stole it from them, but you can see there's that arrow. So, the reason why that's really important is meaningful use is a huge driver. It's a driver for us. It's a driver for most EHR, but really the goal is to get us to that next path where we're using it more effectively.

We, like everyone else, I think, who will present and/or if they don't present this are using other tools; they're using EHRs and PHRs. You may be struck by the similarities. Hopefully you are, because it means that there are important things that we do together. I'm hoping that we share notes, too. And like the previous speaker, we thought there would be pushback. There's no pushback. We share data with private sector vendors.

This is actually – this is my pride and joy, 'cause in six weeks, kind of unheard of in the federal space, but we are federal, we managed to put out a new application in there and get data sharing with a large, proprietary vendor, through a lot of commitment, through a lot of people blowing up boulders. But we managed to do it because we needed that data to get to a virtual life-time electronic health record.

So, when we look at big data, this is what we get – a blender. Lots of stuff going on in there. Our approach? Corporate data is strategic; it's not a secondary data use. You'll still see us; you'll still see that word here, but it's a primary data use. It's how we improve the health status of our patients.

We use products for clinicians, for providers, for leadership, and I would argue for the community, for veteran service organizations, for people that do advocacy for our patients. But in addition, we use it for the communities in which our patients live. Because while the VA is in those communities, we're not, in many times, the primary care provider in those communities.

We have lots of other reports, and I'm sure you're gonna see a lot of these. I'm just going to show some of them to you really in a quick way here. They'll look – they will start looking very familiar, which is positive. It means ten years after we started looking at big data in electronic health records, we have finally arrived.

We have finally gotten to the point that the vast majority of systems are able to do clinical and operational metrics presented, hopefully, in a usable way that it can be used, that people can prevent a care assessment report that shows and predicts the estimated probability of death and hospitalization, and in this case, used that data to target patients, to give them interventions, and to make sure that we improve their health status.

So, I don't have a lot of other presentations on that. I think you've seen 'em all. Graphical user interfaces, huge issues related to them, many of which aren't usable. Incorporation of analytic data, at the point of care to the primary or to the specialist, not being done well anywhere that I know of. Lots of opportunity for improvement. Lots of opportunity for us to take on some of the holy grails in health IT that aren't there yet.

But what we know is that we can leverage information. We can improve efficiency, not just from a fiscal perspective, but from the utilization of time and resources. We can improve outcomes. We can collaborate across the data sources. Interoperability is huge. If anybody – and I know we have a panelist going to speak on interoperability. I was going to say if anybody's figured it out, you can let me know, but she's figured it out. So, she'll let us all know.

But interoperability is huge. What happens at that point of care, in a non-standard way, how I send it across, how I mediate it – first, how I translate it, how I translate it, how I message it, how I mediate it, how I consume it, how I use it, those issues exist. They exist for all of us. Meaningful use Stage 2 has taken on some of the consumption issues, and while many of us think that we have figured out parts of it, I would posit the question to all of us that there's a lot more to do, and there are better ways to do it than we've been able to do it.

I want to just take my last few minutes and talk to you about Vista Evolution, because I want to reveal our warts. This is our wart. Like if it wasn't a wart, it would all be together, and it's not; it's a wart. We got a zillion databases out there. We go in; we pull out; we us things for one thing. We have mobile apps that are collecting data that are not feeding the native health IT system that the provider's seeing. We have other apps that are feeding a silo. We have apps that are Web based that patients go to that are really wonderful for them, but that I have no idea what's going in there. The patient may or may not report that to them.

So, when we go back to what we know are the pain points in medicine, the continuum of care, the transfer of care, the establishment of longitudinal health record, the knowing that at Point A, if I do something at Point C, it's going to make a difference. But you did something, because you're the N of 1, at Point B, that I didn't know about, and it made the whole thing go cuckoo. We're in trouble.

So, this is where we are now. And you know what? It makes sense this is where we are, because we've been doing this a really long time, as are many of you. So, we've got lots of silos out there, and it's really becoming untenable to have all those silos.

So, really, our goal – and you'll see that blue arrow is critical – is this dependency, this recognized dependency on interoperability; the need to make sure the appropriate data comes in to the VA and goes out, obviously with appropriate privacy and security; that we do a federated health record as much as we can; that we figure out how to consume data that's generated from outside.

We look at patient-generated data, as well as provided-generated data. We figure out the right ways to consume them. My argument is that we will be doing this in a disruptive way. I don't see any way to get from where we are now to here without disrupting a lot of what we do. I would argue – I've been a physician 30 years; I just had my 30th medical school reunion – it's time for some disruption. It's time for us to figure out how we can do this better, in a way that is affordable for all of us and try to achieve the health outcomes that we've all been interested in.

The one thing I would caution you or urge you to recognize is the standard data model. This is the non-sexy work. This is the work nobody wants to do. It is really hard work. Data modeling, pulling things together, putting them in appropriate standards, making sure you have semantic interoperability, and then moving towards process interoperability. Very, very difficult, and nobody really wants to pay for it either, because it's not billable. It's your foundational work in your health IT system.

For other people that are like me, that have done an amalgam over the years, well, we got an amalgam of data models. So, our need to clean that up will ensure that everything we do is more effective, will ensure that our use of big data is more effective, will ensure the values – the veracity is better, the value is there. So, that's a lot of work that we have to do in the next four years. Obviously, our framework is one of care coordination, and I would argue this is where big data is.

This is our full operating capability, which I'm not going to spend some time on, other than to tell you new user interface – usability, usability, usability. Patient safety from the beginning. Big data being used from the beginning; it's not an afterthought. The way we enter the data, the way we store the data is accessible, meaningful, and able to exploit the current tools that we have. Projection into the new tools. Areas of semantic Web for big data. We're not there yet, but we're obviously talking about it.

These are the challenges that I think confront all of us: that interoperability, the lifetime record. Lots of these you'll see people at the edges. We're working these at the edges. But we have some holy grails out there in health IT, especially as it relates to big data, reused consumption that we need to figure out how to get at.

And finally, I just want to remind you, I work for the Veterans Affair – Department of Veterans Affairs. It was Veterans Day two days ago. But whoever you work for, the bottom line is it's the N of 1. It's the achievement of health equity for that N of 1. It's really that utilization of the health IT system by keeping the patient in focus that will ensure that we make the right decisions as we move ahead for further development in the electronic health record system, that then, once again, think my dots. That's why I had to do mindfulness, so you'll remember the dot. So, that then feeds the big data system as we go along. Thank you.

Terhilda Garrido: So, good afternoon. Ready for the third leg of the race? So, here I go. I am going to run you through a bunch of slides. So, please feel free to ask questions at the end, plus the slides are available for you on the website, I'm told, afterwards. And so, I'm gonna try to talk to you about how the electronic health record not only supports quality, but through our use of the data coming from – and dare I say it, big data coming from our electronic health record, we are improving quality of care at Kaiser.

So, for those of you that are not familiar with Kaiser Permanente, we are the nation's largest nonprofit health plan. We're actually three organizations in one, even though we think of ourselves as an integrated health care delivery system. We are a health plan that covers 9.1 million lives. We are a set of 37 hospital, and we are a set of 6 independent medical groups comprised of 17,000 physicians. And we actually do quite a bit of business outside. We have outside medical care, of course, that we need to manage and take care of as well. We are a $52 billion revenue. This is old numbers.

We spent $4.2 billion on our electronic health record, just to give you a sense of scale. We call that KP Health Connect, and it's outlined there on the blue. It is a set of modules that we purchased from Epic, and there was a question before about best-of-breed approach. We went with single vendor, single electronic health record. So, all of our 611 clinics have the outpatient EpicCare, inpatient, all our hospitals have Epic

Inpatient. We are expanding that to home health and probably to our SNFs – the handful of SNFs that we own.

We really believe in the continuity of care. It is in those tricky and dangerous transitions of care that bad things happen. And so, continuity of care means also continuity of information. And so, for the patient, that becomes really important, and we believe that we'll have better care for that, one.

And two, also as an implication of that, the data repository sitting underneath, you see it at the bottom there in the blue, is more cogent because it is from one vendor, because it is from one electronic health record system. Okay? That's not to say it's easy. Epic gives us at least 16,000 clarity tables to sort through, and we have full-time staff actually trying to deal with all of those and pulling the data out. But at least there's hope of a cogent view of what happens to a patient throughout that continuum of care for at least the care that's delivered within our system.

And then finally, the other thing to point out is that our patient portal on KP.org sits on top of the electronic health record. It is not independent; it is a window into the electronic health record, which is critical to patient's use. They get the same information that our physicians are getting – a subset, I should say. And probably the single most transformational element of this whole electronic health record – but we'll hit that more later.

So, how big is it Terhilda? Well, ten petabytes, and that sounds big, but hard to get scale. So, I googled Library of Congress, and so ten petabytes, according to them, is about 330 Library of Congresses worth of data. Okay? And that's sitting in our data storage right now. It covers 36 million medical records.

How does it contribute to quality of care? Well, there was an archives of internal medicine study that said findings were no consistent association between electronic health records and better quality. And we at Kaiser would actually agree with that. Plugging in an electronic health record – and I think Glenn and the other CEOs also agreed that it is in the fact that you are changing your operations. It is in the reengineering. It is in the new culture. The new way you do your work. The new scope of practice that we actually are achieving the electronic health records' impact on quality of care and affordability.

At Kaiser, we have seen all of those bullet points, and I could talk at length about each of them, but I won't, 'cause we don't have time. And I'm glad Steve went before me, 'cause I think many of the mechanisms that he talked about, we have in play as well in

our electronic health record, but I'm going to focus on how we're using quality of the information, the data to, in fact, improve quality of care.

So, this chart is just to tell you – the gray dots are where we were before the introduction of the electronic health record, and the orange dots show you where we are now. Now, it's not proof in and of itself that electronic health records improve quality of care, but it certainly has supported it, and certainly we haven't suffered because of it, and most of our leaders and clinicians believe that it is, in fact, a big part of why we've been able to achieve those high performance.

Okay, let's talk about data and information. As I was trying to think about how to structure the fire hose of information and examples of how we are using data and information to improve quality care, I had to give it a little bit of structure. And so, at the most global level, there is health care knowledge and how we are kind of advancing research and guidelines. How do you know what to – what treatment to use? There is an organizational level. How do you know what to focus on strategically? The patient population level, the physician level, and as was talked about before, the most important dot of all, the patient level and the data that's made accessible to them. Okay? So, I'm just gonna give you a smattering of a few exemplars from these levels.

I'm going to start with the health care knowledge level, and I call this "A Tale of Two Studies." So, starting in San Antonio, there was the ALLHAT. ALLHAT was the "Antihypertensive Lipid-Lowering Treatment to Prevent Heart Attack Trial." And it was a randomized control trial. It took 42,000 patients, at a cost of $120 million, 8 years, but what they came up with was that diuretics were most effective at controlling hypertension. Well, that's great. Thank you people of ALLHAT; that is a contribution. So, if you're going to do one thing to prevent heart attacks, it's diuretics. Thank you for knowing – for allowing us to understand and know that. Terrific. Contribution to knowledge.

Okay, meanwhile, in Kaiser, one of our practicing clinicians/researchers had a question. And he said, "Well, what if that doesn't work? What's my second-line treatment? And so, he did a retrospective observational study of 4 million patients, at a cost of $200,000.00, which took 1.5 years. And what he found was that ACE inhibitors and beta blockers are good for that second-line treatment. Well, thank you Dr. Magid. That is also a contribution to knowledge. Now, let's talk about these two studies.

I have a graduate degree in biostatistics, and I would be remiss in not telling you and underscoring that randomized control trials are gold standard. They are the top of the pile in a Cochrane review. They top – they are at the tip-top. They eliminate patient bias. However, with a sample of four million members, you can use a lot of statistical techniques to adjust and control for patient bias. You can go pretty far.

But there are other elements to this design that I want to point out. The ALLHAT study was a limited target group. It was primarily white males. I think they threw in a few African-American males, and I can say that as a Mexican-American woman, I felt a little left out. Dr. Magid, who tapped into the California database, as well as the Colorado databases, took advantage of the bounty of diversity that is California and Colorado. And so, you name it; they've got it.

In addition, the ALLHAT study had controlled conditions. Everyone knew they were in a study. Right? The patients, the physicians. Was there a Hawthorne effect? Did it improve behaviors? I don't know, but I can tell you that that was not the case with Dr. Magid's study. Right? This was real-world conditions, "Hey, doc, I lost my job. I've had the medications for the last few months. Where do we go from there?" So, you can see there are real trade-offs in this approach, but it does – big data does open the door to health care knowledge acquisition.

Okay, now I'm going to switch gears and talk to you about KP outpatient safety net reports. And this is a sophisticated audience. You all are familiar with outpatient population management. Okay? You have a group of diabetic patients. You monitor them. You look for screening. You control their hemoglobin A1C. Okay, par for the course.

What we've done is we've actually applied that same sort of thinking to a narrower and higher risk group of patients. Okay? And so for that, I'm going to drill into an example, and no, it's not penguins, but it's the concept of, in this case, abdominal aorta aneurysms. And so, Southern California, under the leadership of Michael Kanter, looked at some of its data and said, "You know what? Twenty-five percent of our triple-A ruptures were actually associated with failures to follow through on known triple-As. And so, they said, "No more. We're going to do something about this."

And so, they wrote a program that scrambled over those 16,000 databases that I talked about earlier and pulled out not just the diagnosis, but used NLP techniques to look at the progress note, to look at the patient history, to really try to identify, "Who is it that has a triple-A," one.

And then, two, to then look in time did they have the appropriate follow-up at 18 months, 24 months, etc., depending on the size of the aneurysm? They then identified using that program, that data. They then identified 1,500 patients. They assigned that to a nurse, who then worked with the physicians and the patients, did outreach, got replaced orders, and was able to get the appropriate follow-up. Reliable, systematic care. Patient safe care using data to do that, again, in an ongoing way, supporting our

clinicians and patients. We are now using the same approach across a variety of 23 other both diagnosis and medication areas, and that list grows, and we are expanding that across all our regions.

I'm not going to go through this one, 'cause I'm going to run out of time, but you can ask me about it later. I'm going to end with empowering patients. And there have been a couple of allusions again to what is being done with patients, but I'll quote here Dave deBronkart, "The most underused resource in health care is the patient."

We have talked about PHRs and how patients are not accessing their information. What is different about Kaiser is that we have 4.4 million patients/members accessing their information at Kaiser today. Okay? And they have been doing this for the last eight years. They can e-mail their docs. We have about 14 million secure emails going back and forth. This has now become a major care modality. Twenty-seven percent of our primary care encounters are through secure e-mail. Twenty-seven percent; it's huge.

My lab tests, people are looking at them. We have 27 million accesses to lab tests. Scheduling appointments, refill prescriptions, view past visits, etcetera. It's wonderful. But what's most important is how patients are telling us how they feel about this. I think it's empowering. The website has improved my relationship with my doctor. Technology improving relationships? I feel much more confident, and I also feel closer to my physician. I don't feel intimidated anymore. I feel more in control over my medical condition.

It was a good thing for me to look at it and to get it to stick with me that I need to take better care of myself when I saw it in black and white. Our VP of Web services indicated that when she looked at patterns of use, people would look at their labs, click on it, two days later they'd come back and click on it again, click around the health encyclopedia, and then click on that lab test again. So, you could just imagine the patients going through a process. Right? This is a different relationship with their health care and with their health care providers.

In addition to just the patients and listening to what they're telling us, we've also done studies to understand what those impacts are. Many health manager users or KP.org users are 2.6 times more likely to remain members. This is very popular. This is the reason to stay with Kaiser at this point.

Secure e-mail was associated with a 2 to 6.5 percent improvement in HEDIS measures, again adjusting for everything we could throw at it, and obviously high patient

satisfaction rates. We see this as an important element of our future innovation. We have gone mobile. Currently, even though it was only introduced about a year, year-and-a-half ago, 27 percent of our transactions are now mobile. So, the center of mass is shifting, and I would say not only to mobile, but to the patient. So, I think this program is aptly named – Big Data/Little Data. I think the little data may win out. Thank you.

Jan Lee: Okay. I am Jan Lee. I am the chief executive officer of the Delaware Health Information Network, DHIN. We are the state HIE for Delaware. And when Jeff called me and asked me to be a part of this panel and said it was about the most advanced EHRs, I said, "Well, we're not an EHR." And I'm the fourth member that's caused this panel to be very crowded. But after we had chatted for a bit, Jeff felt that this really was a good topic for this point in the program and this panel was where it seemed to fit best, so here we are. I'll try to talk fast.

So we have a problem. The problem, and I don't think this is news to anybody, is that there are numerous siloed sources of clinical information. And I won't try to belabor them all and state the obvious. But information comes from organizations that are not necessarily organically connected or related to one another; and therefore, the information that they generate tends to sit in those siloes. This means that important information is often missing at the point of care, and frequently it is clinically important.

Furthermore, there are numerous professionals that are involved in the care of a patient. I've got several examples here, and I've got citations. And I'm assuming everyone's gonna get a copy of these slides or have access to them, so I won't try to read everything to you. But I will give you a personal example because all health care is personal to someone. *[Laughs]* And so I've had a personal story.

On November 25, 2012, it was a Sunday, I woke up deaf in my right ear and with profound vertigo. And I've spent the last year dealing with that. So over the course of 13 months, I have had 20 medical appointments or activities of one sort or another that were extensive enough that took me away from work, and I have been seen in 7 different practices or institutions, none of which was my primary care provider. That's me. That's one person in one-year period. And apart from DHIN, I don't think that all of those bits and pieces of medical information would ever have gotten assembled in one spot other than me being the courier to carry it all around.

So there's the problem. Different pieces of the puzzle are under the stewardship of different people and how do we get them together. Well, of course, the answer is exchange of information. And at the simplest level, you've got directed exchange, which is a point-to-point transmission of information, "I have it. I share it." And there's a number of methodologies for this. Snail mail back in the day, that's how you used to get your lab results, right?

But there's sneaker net *[Laughs]* hand-carry it to whoever needs to get it really fast or the patient becomes the courier for their own information. Now, woo, we're in the electronic world. We can do point-to-point electronic interfaces, but it's still point to point, one system to another. I'm sharing my piece of the puzzle with one other person, who probably still doesn't have all of the pieces of the puzzle. Secure electronic messaging is gaining in prominence with ONC having promoted the direct protocol as an industry standard.

And representing an HIE, I've gotta say my fundamental heartburn with this is that it is point-to-point, and it still does not provide a queriable repository of information that all can benefit from. So sort of the next level of information exchange is query-based exchange, and there's a couple of different models. One is centralized, where all of the data sources are literally pooled into a single database, which requires normalization of the data at the database level. And for those of you who are geeks, there's issues there. The federated model is that the constituent databases remain separate.

They're connected by a network. A single query hits all component databases within the network. There's typically a common user interface such as a portal. And then you've got the hybrid model, which is you consolidate in a single hosting center, but the actual databases still remain separate databases. When we talk about HIE, it's important to remember that it's both a noun and a verb. The verb is the act of exchanging information. The noun would be the organizations that oversee or facilitate or govern the secure exchange of information.

So here is DHIN. DHIN is a pretty mature health information exchange, and we have both directed and query-based exchange. Our core services are results delivery, so that is directed exchange. It's providing a result to the ordering provider or copy to providers. But we also aggregate that data in a hybrid model and have a queriable community health record.

So the data-sending organizations send their data in. It's hosted and stored and made available through one of three methods: auto print, populate an EMR through an interface – and we have a results delivery interface to the 15 EHRs that are most commonly used in Delaware – and then, of course, you've got the Web portal that can have a clinical inbox as well as the place that you would query the system for results that you may not know about. Current membership in DHIN is quite extensive. We have all of Delaware's acute care hospitals plus a couple of Maryland hospitals that are on our border. Lab Corp and Quest and a handful of smaller independent labs.

Ninety-eight percent of the providers in Delaware receive their results through DHIN. That's as close to 100 percent as you're probably gonna get just because of the normal movement. All of our federally-qualified health centers, all of our skilled nursing facilities. We're getting close to 100 percent of our assisted living. And we've begun a connection with our sister HIE in Maryland, CRISP.

We've got pharmacies connected for immunization exchange. We're connected with public health for the typical meaningful use electronic lab reporting, syndromic surveillance, and so forth. So since I was put in the pot of an EHR talk, what's actually the difference between an EHR and an HIE? Well, EHRs are organized around individual patients. It replaces a paper record of care. And you have to remember that record keeping has kind of evolved from the days when it was just a clinical reminder of stuff you did yesterday or a week ago that you might have forgotten 'cause you've seen how many other patients since then.

It's now also a business record because you gotta have substantiation for how you're billing, and it's a legal record. So there's an awful lot of stuff that goes into an electronic health record that doesn't necessarily have to go into an HIE because the HIE is not trying to serve all three purposes. Most of the data in an EHR is generated from within the system. Now, that's not to say that you don't get external pieces of data as well. And the external data, for example coming in from a lab, may be incorporated as structured data or it may be a referral letter that gets incorporated as unstructured or semi-structured.

Most EHRs now do include clinical decision support and at least modest descriptive analytic tools. And there's a recognition that having some form of record-keeping system is the price of doing business. So it's just part of the fundamentals of being an organization, that you've gotta either invest in paper records, or you've gotta invest in electronic records, but you have to have a record-keeping system. HIEs typically are also organized around individual patients, but the primary purpose is very focused on clinical decision making at the point of care. Data in the HIE come from many unaffiliated sources, and so identity matching becomes a very critical issue in this setting.

Enterprise HIEs – and I would argue that the three colleagues that we've heard from so far really all have enterprise HIEs because they're aggregating data far beyond just an electronic health record. It's coming from many other sources as well. But enterprise HIEs that are fundamentally owned and operated by an organization with a common business identity or so forth typically have more data sources or more data types, rather, but fewer sources – in other words, fewer independent entities – contributing than community HIEs. And I'll give you an example in a bit if I have time. So one of the issues then with a community HIE is the end user really has to decide how much they trust the data coming from different sources.

I'm a broker. I don't change the data. I present it as delivered, and the end user must decide how much value they attach to that and how much they believe it. Community HIEs do struggle with a business model for sustainability. It's not like the practice where a medical record system is the price of doing business. You get to decide if you're gonna participate in a community HIE, and the business case is challenging in some situations.

And then for the community HIE, secondary uses of data, which would be anything other than supporting clinical point-of-care decision making, requires additional tools, technology tools and additional data use agreements. So here's kinda some of the similarities and differences. Now, who gets a benefit out of an HIE? And I'm speaking here from the point of view of DHIN. So we, as a condition of one of the earliest grants we received, had an independent third-party evaluation that looked at the period between 2009 and 2011 and identified value or benefits realization for a range of players. And you can see this for yourself.

Pretty much we've shown that everybody gets value or everybody gets benefit, and this didn't even include a meaningful use analysis. And I'm really excited to see the results that are going to be coming out of our HIE cooperative agreement evaluation that we're in the process of collecting data for even now. There have been other benefit studies conducted, certainly, in other settings. This is one by Humana in Wisconsin. And if any of you know of more, I implore you to send them to me because I'm trying to gather a body of literature around quantifiable value or benefits from a query-based HIE.

It's still a young industry, and there is not a universally recognized or accepted maturity model for HIEs. I personally like this one the best of any that I've seen. It was proposed by eHealth Initiative, I believe. And it basically takes you from, "We're thinking about it. It sounds like a good idea," all the way up through, "We've done it. People are actually using it. We have a sustainable business model," and then that top level is, "And we're beginning to innovate around secondary uses of data or additional services around the data that add value."

And I would say that DHIN is sort of poised right on the cusp between stage six and seven. We do have a sustainable business plan. We are very successful. We are ubiquitous in Delaware. No one would think of trying to do health care in Delaware without DHIN, and we are just now beginning to enter in to some of those value-added things that we believe are going to take us into that next level.

This is an example. We are currently working with public health on immunization reporting. As of the end of October, 73 percent of all entries into the state immunization registry were electronic VXU messages that came through DHIN, so that was pretty exciting. We're working with both health plans and practices on event notification. Care summary exchange, that's a tough nut to crack. Could say a lot about that, but we're working with at least one of our federally-qualified health centers on that.

We are just about ready to go into production with our first hospital on image viewing, and we've got several others teed up. And we're working with public health to incorporate newborn screening records into the community health record. So those are projects we are actively working on right now. They are real. They will be a fact of life within this fiscal year for us.

The things on the right side are a little bit more aspirational, but some of them are fairly near term. They're not outrageous and off the map. And I've gotta quit because time is up. So again, putting all the pieces of the puzzle together still is a challenge. I don't think anybody can claim that they've totally gotten there.

My mantra is if it were easy, anybody could do it and we would have done it a long time ago. It's not easy. There are technical challenges. There are organizational challenges. There are just human behavior challenges, but this is a great position to be in and a great job. So I think that is – and I have some sources here if you want to look them up. That's it.

Lee Fleisher: Great. So we actually got through all the presentations within the hour. In a moment we'll open it up to the audience, so if people want to start thinking of their questions and come to the mic. The last presentation actually makes me think about the issue of there's – how do we know what to present to our patients and our providers? Because you actually talk about this exchange, and we've heard that you increased satisfaction at Kaiser. But do we know what is the optimal interfaces and are we sharing among these, or is the 800-pound gorilla – we heard Epic mentioned multiple times, so the people in Wisconsin really driving what that interface is or is it done locally? So I'm wondering if anyone could comment.

Terhilda Garrido: All right. There are standards that are being established for kind of a minimum set, the CCDA, which actually has quite a bit of information, so I think that's a place to start. Clearly it's not everything, but it does provide diagnosis, allergies, and medications. That information is critical that currently isn't being exchanged in many situations right now. So certainly I would look to that.

Theresa Cullen: I think, though, in terms of how do we ensure that we present information in a usable fashion for the provider, maybe end up with a different solution than a usable fashion for the patient. I'm sure you've all heard of Blue Button. So Blue Button has had many innovations that have driven it to new places based on what providers have told either app developers or other people what they want when they see their data. So ensuring that there's an adequate data stream, which has recently actually been kind of driven by ONC, but I think it is reflective of what we believe patients would like to see. And then ensuring that we present it in a way that is respectful of health literacy, as well as other clinical needs of the patient, is really important.

It's interesting 'cause you had the same experience we did and I'm sure you did. When we opened up notes – I think this fascinating thing has

happened with opening up notes, and Robert Wood Johnson has supported a lot of this work, where all of a sudden patients have access to their entire notes. I trained a long time ago where patients never had access to their notes or you redacted half of what you wrote. So I think it's intriguing that patients are really responsive and receptive to that. And I don't know if that's your guys' experience, but I presume it is.

Steve Peters: We've had a few requests regarding that in the portal. A few requests, but a very small number compared to the number that have been viewed, to edit or questions about what was there or occasionally – someone mentioned earlier about template notes. A template exam where someone would say, "I don't recall you examining these parts," so some that are embarrassing that may have just been credibility issues. That's a problem. But as far as what to display, we've kind of focused on those key things: reports, notes, labs, and clinical notes.

So hospital progress notes aren't there. It's a subset. The issue about problem management, so we're pretty good with medications, allergies. Everyone maintains because the system rewards you for doing that. The problem list management – and I touched on it and we heard a question earlier about how the problem list is bad – is I think we really have to improve this absent relationship between the billing diagnoses and the clinical diagnoses.

Sara Goldstein: Hello. My name is Sara Goldstein. I'm from ECRI Institute. And my question is last month the *American Journal of Emergency Medicine* published a small-scale study of one emergency department that found that physicians were spending 44 percent of their time entering data into their EHR. So my question is we have these advanced EHRs, and we're making all these efforts to improve them, but how can we help physicians use them and use their time more wisely when it comes to entering data and evaluating the data from these records?

Jan Lee: Did that study compare how much time they used to spend in a visit writing the note?

Sara Goldstein: That's a good question.

Jan Lee: I mean you have to enter data one way or another. You have to record the visit, and so that's gonna take some portion of time. I don't know if 40

percent is the right percentage, and I don't know how it comes with the alternatives. So that's just a number. I don't know what it means.

Theresa Cullen: I actually moonlight in an ER, and I think that number's probably right. And we're on a large commercial product where I moonlight that's not Vista. And a lot of that documentation is driven by billing. It's driven by documentation, but it's driven by billing. There's a lot of checks. There's a lot of, "Did you really do that? Did you really ask that question, those thousand review of system questions? Probably not."

But I think the issue isn't how much time we spend doing that. Its how we effectively use the time we have to engage the patient. So there's this whole concept that eye contact really matters. If you know hormones, prolactin gets generated when you have eye contact between people. If all you're looking is at your ER screen, patient probably doesn't have a great experience of care, which we know is one of the parts of the triple aim. So it's not necessarily to me that it's too much time. It's how to make it less disruptive to the provider/patient relationship.

Female 1: If I can comment on that just because I'm a physician, I have to deal with it over here all the time. When you take notes, you can – or least people in my generation can look at the patient and take notes at the same time, and the patient is impressed that you're writing it down. And you can do all the body language stuff. You can't do any of that on the computer, and it does take 40 percent of the visit.

Lee Fleisher: Well, I'll tell you, one of the things that some of the surgical specialists have done is actually had scribes in our institution, so that they've actually used the physician time for the physician contact and they've had others who actually transcribe it and put it into the computer. So I think – and they've found it be cost effective.

Terhilda Garrido: We've gone away from scribes and are using more voice recognition as a potential way to get information in and, in fact, short cutting that transcription time. And actually saving money is helpful. A lot has to do with how the system is configured and what your workflows are. Our medical assistants set up the visit for the physician. They ask a lot of questions.

They pre-populate a lot of things in order to be able to allow the physician to focus on the time with the patient. And, in fact, there's training about how to type while you're talking in a way that is not mechanical but, in

fact, engaging. And I'm using the computer to show them their results, engaging the patient with what the data is. So I think there are a lot of approaches to minimizing the impact of that.

Steve Peters: We do all of the above, so we have backend voice recognition that helps transcription. But we have transcription, which is hard. I'll be the last one to give it up. I've done self-entry and templated and voice recognition, but personally no one could beat me dictating a note. It just takes a few seconds for a complex consult. But the ER is a different place. I would ask, about that 45 percent, is 90 percent of the 45 percent regulatory legislative billing and actually wasn't documenting what the patient was there for?

Theresa Cullen: The one thing I do want to say, this is a holy grail of health IT. We haven't figured this out. We have not figured out how to make note taking really reflect the patient story, as well as our story on our interaction with them. And so lately, actually – I was talking to a friend who's a psychiatrist, and she's really into this eye thing. She keeps going, "It's the eye thing, Teri."

So I said, "Well, we imbed images everywhere, so maybe what we do is we imbed the image." We imbed the first ten minutes of the interaction. We imbed it as a voice video conference, and it's there. And the next time the patient comes in, it's there. And if you have a good NLP, I mean we do a lot of work with NLP, maybe you can pull everything that way. I don't want to lessen your question 'cause I think it's really critical, and I don't think we have a good answer yet.

Lee Fleisher: So how long before we get an answer? How long does it take from the implementation till people are using it in a reasonable way, and when do you think we'll see it working like we'd like it to work?

Terhilda Garrido: We're on a treadmill. We are through the looking glass. We are on the electronic – we are at the Henry Ford Model T version, and the cars are just gonna keep getting better. Cars are gonna get better. They're gonna get smarter, and we're on this journey.

Steve Peters: It's a moving target though. I showed briefly an image where I showed the attending's diagnoses. All of our consults at Mayo have been through documentation training. Why? Well, we get better recording of co-morbidities, more accurate severity adjusted DRG, then we look better in the UHC rankings. Our standardized mortality ratios are better.

And so the words now – the whole note has changed. It's okay. It's just that you have to say – you can't say renal failure. You have to say kidney injury because there's no synonyms in the payer world, I guess. But everyone's learned the lingo and then it changes. So that's new from a few years ago. I'm not sure there's a date when it's finished.

Wyatt Brodsky: Hi. I'm Wyatt Brodsky. I'm a solution architect with Optum, and I spend a lot of time worrying about doing pop health statistics on state Medicaid data warehouses. There are two kinds of information I would really like to have more of that I don't have much of. One is social work information like the patient's reading level in English or whether the patient has a caregiver and whether the caregiver lives with the patient. And the other, which has proven to be kind of problematic in matching because it's so frequently outsourced, is things like intervention programs that aren't considered clinical enough to be worthy of a CPT code. I'm thinking like weight reduction programs, home telehealth programs that are monitoring but not curative. And due to the double whammy of frequently being handled by a thirty-party provider and, again, not being clinical enough to have their own CPT or HCPCS code, frequently don't wind up landing in the electronic medical record even though both of those kinds of information are wonderfully insightful in understanding things like medication adherence. I'm wondering if any of your institutions have been engaged in trying to both collect that data and put it in a place where the people with the data warehouses can do something with it.

Theresa Cullen: I used to be the CIO at Indian Health Service, and when I was there, we embarked on a way to get standard – I was telling these guys this earlier – standard messaging for domestic violence screening that did not have a CPT code, so nobody wanted to pay for it and there were no standards. There was no reason to develop a standard 'cause nobody was ever gonna pay for it. So we developed our own standard working with the Family Violence Prevention Fund, now Endviolence.org. And then we went into sexual abuse, very similar.

There's no good way to record sexual abuse. What do you record? When do you record it? How do you record it? How do you make it safe? Blah, blah, blah. How do you get at it? So huge issues. Actually, the VA and DoD have just, within the last two months, started looking at nontraditional determinants of health. There is a few other initiatives. IOM has an initiative. Previously NIH had an initiative with SAMHSA.

Our goal is to develop the framework that we will be using to identify which of those elements should go into the health IT record and what would be the standard way to record the data. Because my concern has

been that even if we develop the data fields and we start recording the data, unless we figure out how we're gonna have an ability to normalize that data or have semantic mediation of that data, it won't help you because you'll get 20 different ways domestic violence is recorded. So it's a really important space. I think there's more and more people in it. I know the Office of the National Coordinator has also embarked on that. So I think this is one of those holy grails. I think it's finally gonna be addressed in the next two to three – 'cause he's gonna ask when – two to three years.

[Laughter]

Steve Peters: Yeah. I had a comment. I'm afraid to look because I don't want my prolactin level to go up. *[Laughter]* I have a confession that I go the CPT panel for the American College of Chest Physicians. And you raise a very interesting point because CPT has got a lot of codes, and they tend to be lumpers, rather than spliters; although there are codes for things like smoking cessation counseling. And there's a fear at CPT that if there's a code for counseling every human behavior, that the CPT would look like the DSM.

That it would just be more work to code these. So I actually think you could propose what your idea, which is new, to College of Physicians of the Geriatric Society, who could bring this to CPT. There is a forum where new ideas are discussed without putting a numbered code on the table to ask, "Are things that would have value like this or interventions that would be worth recording, separate from the code for a bill," 'cause they will say, "We have evaluation and management codes. You spent 20 minutes talking to the patient. Put it down and just say what you did." Then you've pointed out that then you don't capture that in a way you can use it.

Terhilda Garrido: Speak to the other V, the variety of data that is part of big data, right? And I think there are gonna be a variety of mechanisms to be able to harness and take advantage of that information. So as you're talking about some of those things, we've done studies that kinda link to US Census tracks to try to infer education levels and socioeconomic status. And, again, statistical techniques are wonderful things that allow you to, with a large N, be able to infer pretty well at a larger scale. Secondly, we've also instituted again using some of the mechanisms that were just spoken about.

Exercise as a vital sign. That is institutionalized. That is now, in addition to knowing your blood pressure and your weight, that is a question that is

regularly asked because it's critically important to understanding a person's health. So we're collecting that and we're making explicit efforts to collect that. And then in addition, we've talked about patient-reported outcomes before.

I think that we're at the tip of the iceberg with regard to patient-reported outcomes, and I think that that will be a huge boon to understand many of the kinds of other variety of information that we need to get the full picture, right? It's not just about health care. It's about health of the patient. And so there are gonna be a variety of different mechanisms. I wonder if it won't outstrip our medical society's abilities to keep up with the coding. And we're gonna have to figure out other ways to be able to string that data and associate it with patients in a way that's meaningful.

Lee Fleisher: With patient-reported outcomes – I'm on the Consensus Standard Advisory Committee of the National Quality Forum – the question will be how will the patients enter it, rather than how will the physicians enter it. So the interesting question would be, though these portals, will that be the way it's collected so that it actually can be validated from a PROM perspective. Pie in the sky, but it might happen in a few years. Thank you. Next.

Lydia Green: Hi. My name's Lydia Green. I'm a pharmacist, and I work at Epocrates, which is a mobile health care technology company. I have two comments. One is about what you just said. In Silicon Valley, a movement that's very popular – and I think it goes across ages – is the self quantification movement, where people are collecting their own health care data. And these are healthy patients, not sick patients. So if you go to a meeting of younger people working in health care technology in the Peninsula, you'll see people with things on their belts, which is recording their blood pressure. I've seen somebody who had a Band-Aid on that was recording their cholesterol level. So that kind of data – I'd be interested in thinking if you think that has value because it's coming from healthy people, not sick people.

Jan Lee: I totally think it has value. As an HIE and starting to think beyond just lab results and imaging reports for point of care, as we're now starting to think about how do we leverage this very rich pool of data for population level analytics in the state of Delaware to improve health across Delaware. You can't limit yourself to just what happens in a hospital, and you can't limit yourself to what happens in an ambulatory practice. A lot more happens there than in a hospital, but way more than either one is what happens out in the community and in the homes. And if we can get

access to data from that setting as well, I think it carries us a long, long way in being able to do an awful lot more than we can do right now.

Theresa Cullen: I think the last part of what you said is really critical, so there may be inherent value for the patient. The value for society is the ability to access that data in aggregate, and I'll give you a good example. Dr. Ross Fletcher, a well-known cardiologist at the VA here, did this huge longitudinal study about seasonal variation of blood pressure. And it turns out in the winter your blood pressure goes up, and in the summer it goes down. So we were rewarding physicians for better blood pressure control in the summer, but it really had nothing to do with them. It was just that there was seasonal variation of blood pressure. So the individual patient might not be able to recognize that, but having the ability to collect that data and then analyze it from a big data perspective has real societal value.

Lee Fleisher: Last question.

Female 2: Yeah.

Lee Fleisher: Behind you. Actually, we only have time for one more question if the gentleman behind you could ask.

Female 2: Oh okay.

Male: Dr. Lee, congratulations. I have been hearing disparaging remarks about HIEs all over the country, and you seem to –

Jan Lee: Out of Delaware. *[Laughs]*

Male: – be doing an excellent job. Congratulations.

Jan Lee: Thank you.

Male: My question is are you gathering the data in the HIE from all your sources in real time? So if I move back to Delaware, which I am considering right now *[laughter]* I would be able to, in effect, do a Blue Button and get all my stuff from all the sources at once?

Jan Lee: I'm gonna say a qualified yes. We are getting very near real-time transmission from the hospitals and the data sources that we have right now. It is batched, but it's batched in such a frequent intervals that, for practical purposes, it's real time. We do not yet have a Blue Button functionality for the patient. That is one of the things that we are working toward.

We're going to adopt a mobile app as the preferred tool for patient view, download, transmit with the option for browser based for those who haven't gone mobile yet. Right now today, any consumer in Delaware can, with proper identity verification, come to us and request a copy of the aggregated data that we hold in DHIN. It's on our website. We make no secret of this. It's not wildly popular right now.

We have had a very small number of patients who, in fact, have come to us and requested that. A year or so ago, we actually hired a market research firm to work with us on some consumer research across Delaware to sort of assess what do patients really want, what does the consumer want. What we found is that, not surprisingly, those who are responsible for somebody else's care were more eager to have access, online access to health data than they were if it was just for them. But it was parents with kids, and it was those who were caretakers for those with chronic conditions had an intense interest in being able to see all of that information aggregated in one place.

But the really telltale thing to me was more than wanting to see their own stuff, they wanted to know who else has been looking. There was very intense interest in being able to say, "I get it that it's really valuable that you're aggregating this information, and if I'm ever in an emergency situation, it's gonna be great that we don't have to go on a manhunt to track down all the data. But who's been looking?" And so that's one of the things also that we're pursuing right now is ways to, in a very automated way, provide patients with audit logs of who's accessing their data in the HIE.

Male: You also mentioned something critical to everyone in this audience. You said you have a sustainability model. What is it?

[Laughter]

Jan Lee: It's magic. It's probably different in Delaware than it would be in other places, but our business model for the core services, which is results delivery and the community health record, is that we're an alternative to the US Postal Service. And that works for us because of when we got started. Everybody in the world didn't already have a provider portal that they shared data across. So we say – and we, in fact, asked our member hospitals, "Go study your own organization and determine what the total true cost of delivering health care results through other methods would be."

And they came back and said, "OMG." *[Laughter]* "It costs us, on the average of all other methods: snail mail, courier, fax, everything – on the average, we're spending $1.80 per result that we send out." And DHIN looked like a really pretty good deal after that 'cause we charge a very small fraction of that. Now, what I would say is – and if anybody is like a part of an HIE or thinking about that or whatever, the value – what makes me passionate about this as a physician is the real value is the societal value. It's the public good of having that data in one place. And I am passionate about that, but that's not where the business model is.

People, in general, aren't ready to pay for a public good. They're ready to pay for their good. So we have to figure out ways to get people to pay based on the value they receive from the service. And, by the way, in the process we are building a public value that everybody gains benefit from. So for our core services, it's we're an alternative to the post office, and we're quite a bit cheaper. And then for each additional service that we add on, we have to have a sustainable business model for that service that covers the cost of providing the service.

Lee Fleisher: And on that note, unlike my two previous colleagues from Philadelphia, I am unable to talk about sports at all. So we will end and thank this panel for a great series of talks.

SESSION 4: CAN BIG DATA MAKE A HEALTH SYSTEM BIGGER?

This session raises important questions about the expanding usefulness of bigger and smaller data in health systems. It looks at the financial and productivity cost of collecting data in EHRs and whether it can be reduced. It examines strategies enabled by approaches to data collection that bring community care hospitals into the research enterprise. It discusses whether clinicians, at any stage of their career, are being educated to use data more effectively in practice. It also considers whether data can help forge a more secure tie between care delivered in institutions and ambulatory care.

Moderator, **John Iglehart,** Editor-in-Chief, Health Affairs

Brent James, M.D., M.Stat., Chief Quality Officer and Executive Director, Institute for Health Care Delivery Research, Intermountain Healthcare

Robert L. Jesse, M.D., M.B.A., Principal Deputy Under Secretary for Health, Department of Veterans Affairs

Marc Triola, M.D., FACP, Associate Dean for Educational Informatics, Assistant Professor of Medicine, Division of General Internal Medicine, Director, Division of Educational Informatics, NYU School of Medicine

***Brent James*:** Thanks, John. The topic today is big data. Now, this is not a new topic; it's been around before. It's a reinvention, really, of an old topic, and it's currently – well, the Gartner Group call it "in a hype cycle." This slide shows the Gartner Hype Cycle. Big

> data is actually on the upswing, soon to peak. They then predicted it will drop, go through a little bit of a depression before it finally achieves some real value long term on a stable plateau.

In thinking about big data, though, I could come up with three different varieties of it. It means different things to different people. The first is data mining, frankly. That's one of the older versions that we've seen before. The second is a very common, current application that I would describe as finding needles in very highly-organized haystacks. But I'd really like to finish on the idea of outcomes tracking with drill down as a concept, the data mining concepts.

Back when I was fresh out of medical school, I spent a little bit of time at the National Institutes of Health, National Cancer Institute, technically. This would have been in the late 1970s. While there, I had occasion to visit a very famous, major east-coast academic medical center. They had a large federal grant. It was given to a member of the department of internal medicine at that university. Their basic idea was the big data idea. That prepared about an 80-page data collection instrument. When a patient came to the Internal Medicine Clinic, a data tech would meet them in the reception area. Then that data tech would accompany them through their entire visit, filling in the elements of that 80-plus-page, several thousand-element data form that applied to their particular clinical experience on that day.

Now, it turned out to be really big data at the time, and they stored those data on a state-of-the-art IT system purchased through the grant. Core idea: collect a very wide array of clinical data from many patients, then use sophisticated statistical analytic tools to gain important insights about the treatment of chronic diseases in that internal medicine setting.

The core question, the real reason we were visiting, "How many insights do you suppose that that approach produced? How many papers resulted from this major grant?" If you guessed zero, you got it right. It turns out that there were interesting questions that arose, but very often the data weren't collected in the right format, or sometimes they had data in the right format, but you were missing critical cofactors as part of this whole enterprise.

Some very important lessons came out of this. The first thing that I want you to remember is that clinical data are very expensive, at least at the level of initially capturing – planning, capturing, storing, and analyzing them. My basic working estimate within Intermountain is that I spend a dollar per datum. If I have a data sheet with 30 data elements on it, that I collect for each patient, that's $30.00 per patient to collect and store the data.

Of course, that leads to the idea of big data, that you use data that were collected for other purposes – the investment was made for other purposes – and repurposed them to a new purpose. That leads to a second idea, though. It turns out that good answers

depend on asking good questions. And most often, the questions format the data. To answer a particular question, you need data in a particular format. Yeah, in other words, .3 data systems are very purpose specific. Dr. Ed Deming, the father of quality improvement theory/process management theory, said it nicely, “Aim defines a system.” Nowhere is that more true than when you’re talking about data systems.

Yeah, the right way to think about data mining as big data is a hypothesis generator. You basically have a large database, perhaps collected for other purposes. Claims data is the most common used today in health care – for purposes of payment, frankly. The idea is you generate a very large database across a very broad group of patients, and then you statistically analyze it, looking for associations.

The trouble is, is most of the statistical associations that you discover are spurious; they’re just statistical noise within the dataset. The real work is sorting the wheat from the statistical chaff. Somebody has to go back and figure out what is meaningful, what is not. I remember, at that same time period, working on a large cancer dataset from the CER Registry. I had over 12 million patients. I could detect differences in patient age, with statistical significance, to a matter of a few minutes between groups of patients. Statistical significance loses all meaning. Clinical significance starts to hold the floor.

Now, yeah, the trouble with that is, is the larger the dataset, the more statistically significant but clinically meaningless associations will arise that you have to sort down through. Now it’s interesting. Some of the examples we use of big data at this level come from outside health care. Amazon.com’s a common one. They do similar associations about your reading habits and purchasing habits through Amazon.

For example, your music listening habits. But then they deploy this wheat versus chaff sorting task back to their customers. They raise it to you as a hypothesis and say, “Others like you also purchased this. This might interest you. So, they have a mechanism for sorting out or deploying out that question of, “Is it useful?” Unfortunately, that often doesn’t fit in a health care setting.

Now, there is a second way in which you can use big data, and it’s actually the origination of the term as it turns out, again mostly from outside of health care. For example, GE Corporation makes jet engines and windmills. They build automated sensors that fit on those devices and produce truly massive streams of data. Hundreds of sensors sometimes measuring several times per second. Massive amounts of data that they analyze for patterns of aberrations that indicate possible system failures.

A rough equivalent in health care is genomics and proteomics. They, in doing genetic sequencing, use proteases to break a strand of DNA at different, specific locations based upon base pairs. And then you can reconstruct the entire genome by taking millions of these small snippets and then statistically pasting them back together. Now, these are very interesting informatics problems, and the results can provide you some

information for the treatment of individual patients. It's not clear how it would apply on a broad scale in a health care setting.

Well, that leads us to a third approach. It's the idea of big data as outcomes tracking. Back to Deming, he's the father of process management theory. He argued that the purpose of any organization is to serve a customer. In the case of health care, it would be a patient, primarily. We serve a customer through products or services. Well, he argued that the way that you produce those products or services are through work processes. Any product or service always arises from a work process. He called them value-added front-line work processes, where the value add comes from the customer. The customer gets to judge whether something is valuable or not. You know? Nowhere is that more true than when talking about data systems.

Well, for example, some years ago, within Intermountain, based upon Baldrige approach, we did a key process analysis. We tried to identify all of the clinical processes that make up a big, integrated delivery system. We divided it into two pieces. Think of it as columns coming down from the top. Clinical conditions, where the care of those conditions was processed based. That's true in general. Coming across from the side, we called them clinical support services. Those are clinical processes that are not condition-specific.

So, the biggest single, clinical process we operate inside Intermountain is pregnancy, labor, and delivery. We deliver about 34,000 babies per year. The second biggest is management of ischemic heart disease – heart attacks and other forms of ischemic heart disease. Clinical support services – that's pharmacy, or imaging, or a clinical lab, procedure rooms, nursing services. You see?

Well, we were thinking in terms of clinical conditions. It was really the Pareto Principle, the idea that 20 percent of the factors account for 80 percent of the results. It was also a part of the Institute of Medicine's crossing the quality chasm report. It was the key design principle we identified, the idea that you design for the usual. So, you pick out those big, high, priority, key processes and build around them. And that frees resources in time so that you can plan on a one-off basis for the very unusual.

When we did that, we identified more than 1,440 initial inpatient and outpatient work processes that corresponded to clinical conditions – the columns and the matrix that I just described. Then we prioritized them on the basis of, number one, number of patients involved, number two, clinical risk to the patient and health risk. That ties very closely to the cost of care, just in passing. Number three, internal variability within a particular process.

When we did that, we had a fairly astounding finding: among more than 1,440 initial processes, 104 of them – 62 in our inpatient setting, 42 in an outpatient setting – accounted for about 95 percent of all of our care delivery. This turned out not to be an 80:20 rule. It turned out to be about a 95:5 rule. Well, actually, it was 7 percent of the processes accounted for 95 percent of the work.

What we did next was to build measurement systems around those key processes. Now, a little background. Intermountain, at that point in time, already had some of the most sophisticated, automated data systems you could find in the world for health care delivery. I mean we had the typical financial systems that everyone likes to rely upon today. That's because the data are there. They're generative purposes of payment.

We went a level beyond that. In 1983, a fellow named Steve Busboom established one of the world's first time-derived, activity-based costing systems in the world and would deploy data across the entire Intermountain system. That means we were tracking every lab test, every dose of a drug, every imaging exam, every acuity-adjusted hour of nursing services, every acuity-adjusted minute in a procedure. That level of detail, for every case, against a true cost master, where we sent in management engineers to measure true cost.

Yeah, it was financial data, but it directly reflected clinical decision-making to a degree that you don't find in typical insurance claims data. We had that. It goes a level deeper than that. We had the usual quality reporting. Most of that is generated by government regulation requirements, Joint Commissions, CMS core measures, those sorts of things. But our clinical data went a long step beyond that as well. Intermountain had one of the first electronic medical records broadly used in the world.

When I was a resident, passing through these walls back in 1975, we were using the old Help electronic medical record to manage our cases, now well over 30 years ago. You see? We had all of those clinical data from the EMR.

Well, here's the thing, we identified a method by which you can, using a scientific discipline. A method, in other words, you can figure out what data you need to manage a clinical process and began to apply that method to the clinical conditions for which we were responsible. It was high-priority clinical conditions. When we applied the method, we discovered that despite having one of the most sophisticated automated data environments in the world, we were still missing 30 to 50 percent of critical data elements necessary for clinical management. They tended to be clinical data, clinical outcomes data, for example – intermediate and final clinical outcomes.

Therefore, as we identified them, we started to build those data systems within the Intermountain system. We store them in our enterprise data warehouse. We harvest them from many different sources – from financial data, from lab data, from imaging data, from the electronic medical record, from inpatient data, from outpatient data – pull it all together in our enterprise data warehouse. Currently we have active data tracking for about 60 clinical processes that account for about 80 percent of all of the care that we deliver. We're still building. And hope, over the next years, is to get up to 104 that represent 95 percent. We'll continue building then, too, adding more year over year.

They follow every patient longitudinally over time. Not just for acute conditions, but also for chronic conditions: diabetes mellitus, depression, the common big chronic diseases

that typify outpatient care. Currently, it accounts for about two petabytes of storage. A staff of about 40 people to maintain it. A petabyte, of course, is a million gigabytes. So, a very large amount of storage space for those data, those registries, really. Their primary use is routine, clinical management. So, a true, big data circumstance.

Well, with those data in hand, we repurpose them, but in a very particular way. It's called a learning health care system. You build a data system for routine clinical management. You justify the required major financial investment on the basis of care delivery performance. The short version of Intermountain's mission statement is, "The best medical result at the lowest necessary cost." And we use those data to manage to that end very effectively on a broad scale.

But it turns out, the same data then are well suited to use for not just management, but also for learning. Now, the term associated with that is real dumb, but to really make that make sense, I have to distinguish two uses of data. The first is called "outcomes tracking." In fact, that big data system is an outcomes tracking system. An outcomes tracking system monitors and reports, by definition, a limited set of intermediate and final patient outcomes. Very often we call intermediate outcomes "process steps," by the way, but they're balanced to cross outcomes classes: medical outcomes, satisfaction outcomes, cost outcomes. And the idea is, is that you report them at regular intervals, monthly, for example, and you do it longitudinally over time.

I've tried to illustrate that with that big yellow arrow representing that data tracking longitudinally over time, that track those three big classes of outcomes. Now, within that setting, you add another element. What I know is, is that good answers depend on good questions, and those good questions drive the sort of data you need.

Some years ago, back in the early '90s, Dr. Gene Nelson, at Dartmouth University, called this activity "drill down," and it complements an outcomes tracking approach. Drill down, you see, investigates not a limited dataset, but an extended dataset of detailed process and outcomes data, but over a limited period of time. It has to do with the cost of the data. It's usually a one-shot. I've tried to illustrate it here with these green arrows coming down to illustrate the drill-down concept.

So, within the context of long-term tracking, data that I can justify their expense for actual utility, I have the ability to add those additional data to ask better questions, get in, measure, probably modify my outcomes tracking data system, then get out. Well, that's what's been producing the results. We're able to document more than 1,000 lives per year – people who would have died in the past, who don't today because of those outcomes tracking data and the associated management function.

We're able to document more than $350 million per year in variable cost savings to the Intermountain Health System. The best medical result at a necessary cost. It depends on data, but not just any data. Big data, but data designed for a specific purpose, with an understanding of outcomes tracking, and then the complementary value of drill down.

With that, John, let me turn the time back to you, and I'll stand ready for questions at the end of the presentations. Thank you.

Robert Jesse: So, just to start off and give a perspective of where we're coming at in VA. We have 8.2 million enrollees; about 275,000 employees; a geographic distribution that covers the continental U.S., Alaska, Hawaii, the Caribbean, and Pacific Rim. And that's 152 medical centers, pushing down 900 community-based outpatient clinics, 300 vet centers, and 127 community living centers. So, in scope alone, it's huge.

But when you look at that at scale, what does the product of that – it's – we actually have about 2.2 million unique patients that are in our system. And that 6.2 million is – that's in active care at any one time. We have 1.6 billion outpatient encounters, 9 million inpatient admissions, 3.2 billion clinical orders, 5.6 billion lab tests, 1.5 billion prescriptions filled, 165 million radiology procedures, 2.3 billion vital signs. Terri Cullen mentioned some of the work that Ross Fletcher had done with that in the prior panel. Two billion text notes, which is hugely enriched with a lot of information.

And just to do it, I asked them, "What did we do yesterday?" So, 419,607 unique patient encounters, 2.4 million lab results released, 553,000 pharmacy fills. And all that data can be accessed in some way through over now 800 data management tools that are used across many domains. And I think Steve Fihn may talk to that in his talk tomorrow.

One of the perks that we've taken is that there truly is an intersection of IT and health care, and we call that transactional quality and management. And there's several principles I just want to go through quickly, because I think, in many respects, this is sort of expressing a lot of the same things that Brent James just talked about. But the principle – the guiding principle is that if data is needed to manage the patient or the system, it must be acquired through the workflow process and not through retrospective data collection. And this is actually one of the biggest problems we have in health care today.

Quality data in analytics is still a clipboard operation. We may use tablets; we may use laptops. But fundamentally, we're taking data out of one computer and typing it into another and then post-processing it. And if we really wanted to get to the leverage of big data, it needs to be a very different construct.

Principle Number 2 is that solutions must make the work easier and not impose undue burden and require rework. We found this out very early: you will never get a clinician

to do the kind of work that needs to be done to get data into a system in real time if it requires them to do more work, or if it does require more work, it has to be perceived to be of such value that they're willing to take that on.

Principle Number 3 is that it needs to be real-time visibility into that system, and it's transparent across the enterprise. One of the biggest challenges, one of the biggest, I think, risks in data and health care is the siloing of data. And you get into situations where people are bartering their data with somebody else's data. And fundamentally, everything needs to be – it needs to be visible; it needs to be transparent. And, of course, that raises huge challenges with security. But if you don't have that true continuity of data across the system, you'll be in – you'll not succeed.

As that all comes together, it's not just clinical data. Part of the real value is – and particularly in a system like VA – is when we can marry clinical data with administrative data. And Brent James talked about how they do that in Intermountain Health. But in order to deliver evidence-based care, we have to have evidence-based management. And I think this is one of the real things that falls apart often in health care. And frankly, there's a whole lot more evidence about how to manage large systems than there is evidence about how to manage diseases in the delivery system.

And then finally, complexity must be managed. As we get more and more and more – not just the data streams get more complex, the diseases get more complex. You know, just everything we've known about health care, every one of those diseases that I studied in medical school, back in the '80s, the kids are studying now. Now you have overlays of genomics. You have overlays of proteomics. You have overlays of all the other economics tying these things together. And the simple approach to any one disease just doesn't exist anymore. The complexity alone has become mindboggling.

The second thing is that we talk about electronic health records. The world does not need another EHR; that's the last thing we need. We've got many good ones; we've got great ones. Vista is a great one. But the current construct of an EHR, which is essentially a digital version of a paper record, it generally is one provider to one patient, is not sufficient for managing health care of the future.

So, we've taken an approach through a program we call the Health Informatics Initiative, looking at what we call health management platforms. And this is the platform. We believe moving forward's gonna be necessary to manage this big data, to manage these complex conditions. But it fundamentally has three components. The first is a provider facing, the second is a patient facing, and the third is system facing, and I'll talk to each one of those for just a second.

So, the provider facing allows us to transition from this model of team – you know, of an individual provider towards team-based care. And it allows the new to manage panels of patients. It allows providers to manage tasks across multiple providers, to ensure that things get done that need to get done. It allows you to move your health informatics systems into role-based visions.

So, for example, an emergency physician doesn't want to open up the entire record; they want to open up a complaint-based view of that electronic health record that allows them to manage the urgency. A primary care provider who's managing longitudinal care of chronic diseases needs to see a very different structure. It needs to be workflow driven. And when we really can drive it through the workflows, that's the most fundamental way we'll be able to capture data in real time. And I'll show you an example of that. But it also puts data in form that can be both comprehensive, that can be coded.

We can then use that data, pulling it out in real time to deliver cognitive support. And I don't use the term "clinical decision support" for a very reason. So, you heard about the example of Amazon. Amazon doesn't give you decision support; it gives you cognitive support. It says, "You looked at this last time. You can now make a decision. Does this interest you?" In health care, we really have the opportunity with big data to say, "Will people who treat patients like yours, that you're seeing today, do this?" And those who do this versus this have the better outcomes. And so, it really is not – it's not about decision support; it's about cognitive support. But in the end, it's about knowledge generation.

Patient facing. I firmly believe two things. First of all, true health care reform will occur when individuals – patients, whatever you want to call us – own our own health information. Right now, in any individual's health information, it's almost likely to be hostage to some health system or its IT provider. And, in fact, individuals should own that information. And when that happens, the continuity of care ceases to be a provider function; it actually becomes an informatics function. And I think, as we move towards that day, it becomes real important. And that will happen when patients can contribute to their own record in the management of their own care, or they can assume a much greater role in there.

Right now, we're on the cusp of moving a lot of data that is patient generated into these systems. And this is a real challenge. Nobody knows how to deal with this. You know, even in our system, we saw how many billions of vital signs we have. Well, guess what? We've got patients at home, with home-based systems, that are checking their blood pressure two or three times a day.

And how does all that come in? And how do we annotate that data as patient generated versus system generated? And then which one is more valuable? Because frankly, I see patients whose blood pressure in clinic may be a little bit high, but they bring me in, or we have transmitted in days and days and weeks and months of blood pressure readings all that look great. And I know if I change their medicines the next time they come in, they're gonna be hypotensive. And we've seen this with a number of conditions.

So, we really need to look at the great expanse of activity that patients undergo that's not within the view of our system, but that can contribute data to markedly improve their

care. And then we need to make sure that the patient experience is taken into the consideration of design of these data systems, of these, as we call it, the cycle of the health management platform, because frankly, I think, if we can do that, then the progress note stops being a medical-legal document and becomes an instructional – an agreement – a documentation of the encounter that truly gets to its essence.

And then the system facing. You know, as my position in VA health care, I have this very large patient. It's called the VA health care system. And I fundamentally believe that you can't have health patients without a healthy health care system. And it's the ability to look across patient records that really gives us the power of population data. We can look into these systems in a very large scale and really understand, "What is the best process? What is the best device? What is dangerous? What is risky?" And frankly, if we really do this right, many of the experiments, many of the clinical trials that we're doing today, costing millions and millions of dollars, have already been done. We just need to look into those records and find them.

So, when ensuring the health of the health care system, we really can serve the needs of a large variety of stakeholders. And I'll show you a couple of examples. But the health management system really needs to support this integration of management and information systems, standardized data, dependable quality. You'll hear this time and time and time again.

And the best way to ensure good quality data is to make sure it's good going in and not having to be post-process gleaned. We need real-time data flows, as I said. Data collection is integrated into the workflow process. Our reports are flexible, are constant. We talk about registries. You know, if we can look across the system, we can build a registry of heart failure patients. Well, every provider, or every department chair ought to be able to build a cohort analyses. I even hesitate to use the term registry of all the patients that they're taking care of. I should be able to say, "Show me all of my ischemic heart disease patients who have a dyslipidemia and where are they now." Not their LDL, because we don't measure that anymore, just whether they're on a statin.

Actually – well, that's a different story. No, we actually did that about ten years ago for post MI patients. We said, "Don't measure the LDL; they need to go home on a statin." That's interesting. But so should patients. Patients should be able to come in and say, "Show me all the other patients like me and how they're doing controlling their data – their diabetes. And if they have that level of access, it changes the whole scheme.

So, we can also pull data out of text-based sources. We're doing a lot of work in the natural language processing, as Terri had mentioned earlier. And I think it's hugely exciting about the visibility that's gonna give us into those systems. Our kind of prototype of this is called the cardiovascular assessment reporting and tracking system, where actually the Cs now changed to clinical. But essentially, the way we build – we do the cath reports generates all the data that's needed, both to manage that patient and to manage the cath system nationally.

And so, ten years ago, when I became in the VA the national director for cardiology, they couldn't tell me how many cath labs we had. And today, I can tell you how many caths we did at the end of each day. Not only that, there's triggers, and if there's a major complication, it sets up a system where we're doing external peer reviews of all major complications, starting within 72 hours. And so, it writes the cath report into the note of the patient's chart, but at the same time, all the data's rolled up nationally. And these are the levels of interest we have to do.

And we can use this for patient safety. We use it for device monitoring. We work with the FDA. Monthly we meet with me and talk about problems we have with devices. I talked about the quality systems that we have. We're now coupling in pilots with RTLS to look at real-time location tracking and RFID to look at exactly what's being used in these reports and track equipment and stents and devices down to their serial numbers and manufacturer dates.

So, the use of high-level analytical data, it's patient management population resource planning. Steve Fihn will talk, I think, a lot about this tomorrow, but we literally can risk stratify our patients now and push this data out to the primary care providers or specialty care providers, so that they know which patients in their panels, in the cohorts that they're managing are the highest risk. And in that 80:20 or 95:5 rule, you can focus on the patients who are most likely to get into trouble.

We can map the geography. The right is likelihood of admission or death. The left is the likelihood of admission. You can really see where your hotspots are. But these raises challenges, too. There are always privacy and security data. And particularly in VA, being in the government side, our standards are very, very, very tight. And when we get into trouble, we get into big trouble. Data quality and validity is still an issue, even when it's frontend put in by providers. But it's getting better, and the more you can standardize the data input to the workflow, the better it gets.

There's a lot of noise. The simple example right now, every implantable device, meaning cardiac device – pacemakers, defibrillators – we literally have the capability of looking at every heartbeat that patient has. Every heartbeat they have. Well, that's an awful, awful lot of heartbeats. But what's in there? There is a clue. There's a signal in there. And in fact, the folks that design the GE engine-sensing problem are also now working in health care, because that's what they do. It's big data signal and noise processing. And some day, we may find the signal in there that's gonna give us the real trigger we need to know.

We're gonna definitely need new competencies. Most physicians understand a bell-shaped curve. That's about the extent of their statistical knowledge. We try and do a lot of things to move big bell-shaped curves a little bit instead of focusing on the tails, where the real power and action is. And I think that's the value of being able to find who is in those tails.

Natural language processing is gonna open things up, 'cause, as you heard, we're more and more likely to start dictating now, as a way of getting things, and you gotta figure that out. And it's expensive.

Hardware, software, expertise. And doing it at a small scale in one place is easy. Taking into scale international system is not. So, our day's increasing logarithmically. There's huge potential. Huge potential to improve quality. And most importantly, to improve the efficiency of care because fundamentally, efficiency drives both quality, safety, and value. There's a lot of new technology coming down the road, and one of the real challenges is the more heavily we invest and lock ourselves into certain things, the less flexible and dynamic we can be.

And then there's a high cost to this. But Brent James also explained a little bit of this is it's actually leveraging the frontend investment cost to the potential savings, to the potential improvement in outcomes. In the end, that's the value equation that we need to build in health care. We need to change the driving force in health care from performance to value.

So, anyway, I'll stop there. Thank you very much.

***Marc Triola*:** Hi. Thanks so much for having me talk to today about a slightly different perspective on big and small data, and that from one of a medical school and the role of big data in education of and for our young physicians.

So, medical education is a very large industry, as, obviously, is medical practice. We have about 141 medical schools in this country; about 80,000 medical students – this year was the most number of students who both applied and entered medical school in history; 110,000 residents – that's house staff, doctors in training; and about 850,000 physicians in practice.

So, we can see right here that the sort of the burden of education, as we're thinking about it, is certainly across the spectrum, but much, much, much more so on physicians in practice when we think about new and emerging technologies like the analytics and other approaches associated with big data.

So, we know that big data and analytics can help doctors deliver better care, or we've seen some great examples of that. But the power of this may still lie in its potential, but it's gonna happen. And we're very interested in how we can use big data and analytics to produce better doctors.

So, why are we really thinking about this now? And the first is, is that, as you've heard, everything today and everything that you'll hear at this conference is that the pace of accelerated change in health care is dramatically increasing. The differentiation of what it means to be a physician, a nurse, and any other type of health care provider is becoming increasingly more heterogeneous in a very healthy way.

And the country and the field of biomedical care demands a diverse physician workforce. We can no longer sit by and cookie-cutter produce physicians using the standard models of medical education.

Medical students themselves are becoming increasingly diverse. Not just the demographics of students, but their interests, their trajectories, the types of jobs and careers that they want to have. And we not have, since we've moved to a much electronically-driven medical education and higher education milieu, we have the opportunity to collect data about our students and about our curriculum to use it, just like we've heard about our patients, to improve how we train them. And, of course, we have new analytic methods. We have new math to work on this.

So, here's a great quote from my perspective. This is from the Bill & Melinda Gates Foundation, "I know more about my 11-year-old son's sixth-grade basketball team than the average college faculty member knows about their incoming class in terms of key variables that are going to make them successful or not successful." And I think that if any of you are a faculty member, if any of you are teaching students, this really rings true. We know almost nothing about our students. We know nothing about them as individual learners in terms of their own strengths and weaknesses, what they did before they walked in the door to our medical school, what happens to them afterwards.

And we have the opportunity – we have the obligation to think about this in a fundamentally different way. And it's a great time to do this, because medical schools across the country are changing. They've been changing more in the past 10 or 15 years than they have in the previous 100 years and dramatically so. We have some fundamentally new models of medical education that are drastically different from the medical school that I went to.

We have new technologies to teach our students, like simulations centers, human robotic simulators, mannequins, standardized patients. We have new ways to assess our students, our house staff, and our practicing physicians. The electronic tools of learning, as well as the use of all of the clinical data and the big data of health care as a medium for education, both from internally and from the insurance companies, and data from other outside learning resources, such as MOOCs, these massive open online courses, and even data from other schools.

So, just to talk just very briefly about new models of education, our medical school has really embraced the fact that we need to change that. The health care environment has changed, and it's our obligation to keep us. So, we now offer a three-, four-, and five-year medical school track as a beginning step towards that differentiation for our students.

We have 17 students who just started in a new 3-year medical school, and they're admitted to their residency program and medical school at the same time before they come in the door. These are special people who have to know what they want to do with the rest of their lives. And they have a continuum experience throughout NYU, very different, and I think one that's really going to be quite compelling.

So, within the world of education, just like in the worlds of clinical and research – the domains of clinical and research, we are beginning to apply this big data approach. And so, what we've done is created and education data warehouse that is a parallel to our research data warehouse and our clinical data warehouse. And this data warehouse includes virtually everything about our students, house staff, and faculty that we have electronically. And I'll show you some examples of those data in the later slide.

And so, if we think about this, as we collect these data, just like we collect very fine-grained data on our patients, we can come up with a very clear picture of their individual strengths and weaknesses, their interests and their experiences, and essentially we can sequence their educational genome and design a curricular or teaching intervention for them, and a personalized learning experience much as we would in picking that ACE inhibitor versus the hydrochlorothiazide for the patients whom we sequence their actual genome.

So, why think about this, and why change? Well, this is the lecture schedule from my medical school, from 150 years ago.

And these folks all have tenure, so they're actually still the course directors now.

But this is doctoring with a capital *D*. These are the inventors and originators of a lot of American health care in American medicine. And we don't want to lose this. We don't want to lose the imparting of the profession of doctoring and the skills of the physicianship. But we need to figure out a way to move away from this, not sacrificing these skills of communications, the skills of interpersonal relationships and patient rapport, and move away from this and more to a model that looks a little bit like this.

And in fact, if you look at this model, this is very similar to some of the slides that we've seen before, where we have the opportunity to think about how we can use data and analytics to take our students and our house staff and our practicing physicians, assess and teach them, using learner data and peer data, and then layer in our analytics and predictive models and display those back to the learner themselves, back to their teachers, mentors, and faculty. Not replace the decisions and the judgments of the humans involved, but support their decisions and, of course, suggest some next steps and then create customized learning paths or potentially circle the person back into remediation, and have this become a routine part of how we learn in medical school, how we learn in residency, and how we maintain our competencies as practicing physicians. And this is very doable and very possible, just as we've heard – as is the case with patients themselves.

An important part about that is the use of clinical data in the educational experience, the use of real clinical data from our health care systems and hospitals. And this is something that I think is going to be tremendously powerful and tremendously transformative. We're lucky in that our medical school and medical center are a single combined entity, so we don't have political or social organizational barriers between using those data.

But think about how tremendously powerful it could be to use not in an anecdotal sense, not a single case presentation sense, but to use large-scale electronic medical record data to teach our students, to teach them how to model, analyzing and using these data, just as they will when they become scientists who are working with the analytics on the clinical side.

And it poses some really interesting questions. What patient outcomes can we be – can we use to monitor the impact of our curriculum, or curriculums across different schools. These are called the educationally sensitive patient outcomes, or ESPOs, much of which are impacted by system factors and confounders, but there's some tremendous opportunity to determine them.

And can we think about how we can use the combination of clinical data and the combination of electronic learning data to help our faculty, who are extremely busy, who are being pressured to deal with and learn a lot of these new things, but who still want to provide a high level of

education? Can we create faculty-to-student support systems that use these educational genomes to help them provide more appropriate and tailored guidance and feedback to our students and learners as they go forward.

So, we have this great opportunity in health care. We have an opportunity in health care that most of higher education doesn't have. We have this educational data ecosystem. We get students who come into medical school with a ton of data, when they get to us, on their primary and secondary applications, data that we can bring in from college. And then as they go through this continuum – not different experiences, but a continuum of medical school residency and clinical practice – we collect a ton of data on all of us. And most of it's siloed, most of it is separate, but it will be integrated, and within a single school, we have the opportunity to integrate it.

And most importantly, we could link this to clinical patient outcomes and begin to understand the impact of this educational experience and the growth and maturation of clinical experts and how that impacts improved care for our patients.

So, this is an amazing opportunity. This is a transformative opportunity for medicine, just as it is for clinical care, just as it is for our research endeavors. We have the opportunity to provide scalable personalized learning for all, just like we do scalable personalized health care for our patients. We can empower our learners to use their own data, just like we heard empowering patients to use their own data. We could get a holistic view of the learner context, both things that happened before they came to us and after. And we can think about these educational decision support.

So, we can do that from the school perspective and help these students learn better, but how are we producing students who can actually participate in this future environment, when they're going to be dealing with all of the amazing tools that this audience is creating? And this is not something that's far off. You've heard some mention of things like connected health devices. Well, these are devices today that our medical students, house staff, and even our patients have in their pockets and in their hands.

So, in the top left is a pulse oximeter that hooks up to your iPhone. It's like 35 bucks on Amazon, and I guess Amazon Decision Support would have you buy this thing, then use clinical Decision Support to use it. And this bottom left is an iPhone EKG case. It gives you a single-lead EKG machine on your iPhone. It's 200 bucks. And this is a handheld ultrasound machine, and some medical schools are actually now giving every medical students a handheld ultrasound machine when they walk in the door.

And this is Google Glass, augmented reality that overlays, on top of what you're looking at, information about the environment around you. So, you can imagine a medical student or a house officer having these devices in their pocket and having the ability to generate more clinical data than a hospital could have 10 or 15 years ago. And this isn't even the genomic data or the protein data. This is the clinical data that they're generating at a higher rate and density than we ever have before.

So, where does this all fit in? This is our approach to this challenge at NYU. We have an education data warehouse that I mentioned that brings in all of our learner data about our

curriculum –, everything that we teach our students, house staff, and faculty – math to medical vocabularies, our learning management system, our portfolios, our evaluations, the exams our students take. Their performance in all of our simulation centers are all brought in to our education data warehouse that goes out to research data marts and reporting and analytics. I'll show you some examples.

And then, most importantly, we've now merged our education data warehouse with our Epic clinical data warehouse. And so, we can now link everything that's happening in the classroom, or in the simulation center, to what happens when those same folks are participating in care on the inpatient side, or in our NYU-owned practice network in the ambulatory setting. And this is just a huge opportunity for us.

So, that gives us some really great tools to think about how to move our curriculum forward. We're not just limiting ourselves to just the NYU-owned data in Epic. We have some great opportunities. New York State publishes with their SPARCS data. Every single inpatient discharged in the state, at the patient level, identified by the provider. So, we can then use that data to rebuild the clinical distribution of cases at all of our affiliate teaching hospitals, even if we don't have direct access to their electronic medical record data.

And we can then, therefore, go back and say, "Are we teaching, in our curriculum, to the burden of disease that's present in the patients that we're taking care of? Are we teaching the stuff that these kids need to know?" A simple question, but one that has been anecdotal up until this point, and not truly mapped to the changes in our clinical disease population and changes over time.

We also place a great value on giving, especially our medical students, real-time views on their data themselves. Our students have access to their own dashboard, just like we do, as health care systems, and just like our patients would do in a personal health record. And so, our students can see how they're doing and being evaluated on qualitative skills such as communications and professionalism, on leadership and other skills like that.

They can see how they're doing on all of our knowledge assessment measures, broken down by domain, across exams, across different assessment and evaluation approaches. And they can see in real time what patients they're seeing, whether or not they're having an adequate education experience in terms of supervision and mentorship, and what procedures they're performing.

And sort of the ultimate goal and where we're at now is how can we use these data to reflect back to the students to begin to think about how they're managing their own panel of patients. And so, this is a dashboard that we're rolling out now to our students, which on the bottom shows, in purple, the types of cases that our students are seeing, and in green, in real time, the last 30 days, the types of cases that that service has been seeing.

So, the students and their mentors can begin to see if the clinical experience they're having during medical school mirrors the clinical demands of that field in practice. And then we can make course corrections along the way to make sure that our students are having a customized and tailored fit to what their ultimate goal and practice goals would be. And this translates back into milestones in terms of case exposures. That's not equivalent to quality, but at least we can guarantee the exposure to the minimum set.

And very clear red, green, yellow views for our students as to whether or not they're meeting their metrics, and easy feedback from faculty who can then make evidence-based decisions on where they should go next and what their educational experience could be.

And we've parlayed these data into a three-year-long big data curriculum at our medical school for our medical students. This is funded, in part, by the AMA Accelerating Change Initiative. But really beginning to think about how can our students leave our medical school and leave our residency programs, prepared to manage big data in their clinical practice and in their clinical management of patients themselves?

And so, this has just been a wonderful experience. The students are enthusiastic. The health care environment is very enthusiastic about this, and we have this great opportunity, and this tremendous power of data integration that will bring all of this together.

And I'll stop there and thank you.

John Iglehart: We have about 20 minutes for questions. I will begin with a question or two but would certainly welcome questions from the audience. When you ask your question, it would helpful for the panelists if you would identify yourself and your affiliation. The first question – I'm struck that these three speakers represent three very different types of systems, and my general question is to all three of them, really. You've explained well, in general terms, your systems and how big data applies to them; but my question is what are the challenges that your systems face as you implement and exploit the power of big data? The human challenges? The structural challenges? The financial challenges? And Brent, we'll begin with you since you were the first speaker, and the floor is yours.

Brent James: I see a couple of real challenges, John, in that regard. Perhaps the two biggest are is developing this vision for building the data for purposes of managing the frontline work processes. Turns out it's a major, major tool for better care. Most people still rely on what they have. They say, "We've been collecting these data for years." It means it's mostly financial claims data. And just the vision of the thing, that it requires a different data set. And the science behind it is actually fairly compelling, so a new vision for what should be collected broadly.

That ties into the second. We get national efforts that mandate particular data sets and they don't align to that vision. Believe it or not, some takes the form of national quality data that are not useful for improvement. It's collaboratives where we don't use the rigorous methodology for figuring out what we ought to be tracking for a particular condition. Some do it well. Some do it poorly, but the whole field would massively improve if we could approach it from a science basis, evidence-based basis as opposed to kind of a craft of databases where in my experience or let's ask the experts sort of a basis would make a real, real difference.

Robert Jesse: So I think one of the risks is the more data we have, the more we got lost in the data. And in many respects, I've been concerned that the quality itself has become a statistical function and it's stopped being about the patients. So the real challenge is how do we always make it about the N of one and have big data provide the insight to millions. So we start treating everybody like the average that we see in the large amounts of data rather than making it back around the individual. I think this is a lot of both the blessing and curse of having too much data. But getting it all together, focusing on the patient, reducing harm, making things safe, making it about that patient; and, yet, at the same time leveraging all we know toward improving the systems as a whole.

Marc Triola: Obviously I agree with everything that's been said. I think that a lot of the common themes have been reiterated. I guess one that I'll add is the fact that earlier someone mentioned in passing about a patient donating their data. And I think that that's a symbol of the fact that there's oftentimes a desire to integrate data that is held up by policy or regulatory procedures or things like HIPAA or FERPA on the student side, which is the analog for student data. And I think as organizations, we need to really make sure that we have rational policies that allow us to certainly protect the individual, protect populations, but can do something with the data and make use of it. The greatest travesty would be if those things prevent us from drawing the conclusions that would ultimately really help the population, so rational policies. I know it's a crazy concept, but it's something that would definitely be needed.

John Iglehart: Marc, you're in Washington. Rational policies? Glenn Steele pointed out this morning that it took his organization 15 years to reach a return – a positive return on investment, but he also noted that for the last 5 or 6 years that the return has been growing. How do your systems define return on investment? Is it all about money? Is it mostly about quality? What are the other factors at play here? And you can begin, Brent, if you will. Thanks.

Brent James: As _____ the higher quality almost always drives lower cost of operations. When I'm talking to my clinical leadership inside the system, I tend to lead with major improvements in clinical outcomes and follow on with the associated cost savings. When I'm talking to my administrators, I tend to lead with the cost savings and follow on with the clinical improvements. But the fact is they always come as a package deal. Best medical result at the lowest necessary cost, that's our mission.

I can completely cost justify this investment, though, on pure financials alone. And I think just as a good manager where money is important, cost of health care is important; that that's one of my obligations. So we can completely justify this on the financials alone. The fact that we get it by better patient outcomes, of course, is what makes it so very, very attractive.

John Iglehart: Did it take your system the 15 years that it took Geisinger to reach a positive return, or were you –

Brent James: Oh, we actually started to show a positive return on investment about two years in, so it didn't take us 15 years. Yeah. Now, I have an advantage over Glenn, and that that's activity-based costing system. So from day one, we had really, really good cost data. So I could track cost outcomes. That was a major advantage that I stumbled into by pure dumb luck when I came to Intermoutain.

John Iglehart: Bob, I presume a large public system like the VA system defines return on investment in a different way.

Robert Jesse: I think ours is driven a lot more by the clinical outcomes. Our informatics system, first of all, was not an upfront purchase. It's been an investment that's grown iteratively since the inception of this five or so years ago. But to us, the – and it was literally built by clinicians to support clinical care. So the return on investment really is in the ability to improve clinical care. And frankly, it's very difficult in government, for one, but even in health care in general to do the kinds of that it really takes to do this well. And that's a challenge too is we try and drive on value because how do you leverage this?

John Iglehart: Marc?

Marc Triola: I think that that's even harder to define within a medical school. Medical schools are truly nonprofit. And this was an investment that our medical center was clearly making on the clinical side. And I think most medical centers have seen that this is gonna happen. I mean this is a clear investment of value, but this was something new for our education side.

Building an educational informatics team, building an infrastructure for our education data warehouse that was in addition to the clinical data warehouse. And our ROI is not gonna be a financial one. It's gonna be about the quality of our educational program. It's gonna be about the

quality of the physicians that we produce and the impact on the future care that they deliver. It's gonna be on the reputation of our school and on informatics and data being a driver for our transformation and our adaptation to 21st Century medical education.

John Iglehart: One of the imperatives, I suppose, of a learning health system that has achieved a lot of credibility is around building teams for care, team-based care. When big data meets teams, what happens and how does NYU begin to educate physicians, nurses, and other practitioners in teams in relation to big data?

Marc Triola: Well, I mean the simple answer is when you look at the data, when big data meets teams, it shows that better teams are really good and that they perform well and they result in more efficient care that's of higher quality. So big data has done a lot to really validate the need for high-function multi-disciplinary teams, which is a wonderful thing. At our medical school, we have a curriculum for our medical and nursing students. They take a year-long curriculum together on the competencies of teamwork and team-based care. And this leverages our informatics infrastructure in that bringing medical and nursing students together, for any of you that's involved with this, is logistically extremely difficult.

The two programs could not do more to design educational schedules that were more incompatible than they are. So you use a lot of asynchronous instruction and simulation-based education to bring the learners together to teach them about the competencies of team-based care and then layer that back in when they're in the clinical environment to learn more about that. But I think if you were to ask any of the large health care organizations here, especially the VA and their home-based care, it's all about the team. And that is such a critical aspect for the future of health care.

Robert Jesse: I agree. The real challenge in team-based care is to move to a way that we truly do work as a team, as opposed to allocated responsibilities. And it's a huge transformation in both how we respond socially and how we think. So one of the things we are doing is actually we are investing very early in the training cycle. So we're funding programs on interprofessional education. We're funding programs that really begin that level of team-based training down into both medical school and residencies, rather than having people come through those programs in the traditional models and then have to relearn that process when they come into an active health care environment.

I think this is a whole new world of metrics. How do you measure team-

based care? How is that effective? We can look at proportional models, how many people are there per one M.D., for instance, but in fact, the relationship with the patient is what's really important. And fundamentally what we're trying to do is change health care from being about an encounter, which fundamentally it is today, to being about sustained relationships. That's why that team and the relationship with the patient becomes so very important. It's gonna take an investment deep into the training cycles and, I think, many years to happen, but it's happening, and it's happening relatively quickly.

John Iglehart: Brent, do you have a comment on that question?

Brent James: I'm having trouble hearing the other speakers a little bit, John, so I'm not sure what to add. I tell you this, when you're doing process-based management, its' all teams and it's really a series of tools to make teams work together more effectively. So it's an integral part of the entire structure. We found that in reporting data back within our system, team-level data works at least as well as individual-level data.

Robert Jesse: My comment about health management platforms is really trying to change the whole architecture of health IT to support that team-based care, which I think needs to happen as well.

John Iglehart: Speakers throughout the day have mentioned policy in one context or another. Marc talked about rational policy. If the three of you were testifying before a congressional committee and you had one recommendation –

Robert Jesse: I get PTSD when you say that.

[Laughter]

John Iglehart: One recommendation you'd make to Congress about improving quality, particularly in relation to big data. What would that be? Brent?

Brent James: Boy, that's hard. I think I would recommend that we use a scientifically rigorous method for determining the kind of data that we collect and share. That would probably be the single most important thing.

John Iglehart: And would that be –

Brent James: There's a method, you know, and most people don't follow it. It's the way that we design data systems for randomized controlled trials. We actually discovered it while working on the strategic framework board of the National Quality Forum. Their evidence-based recommendations, how we built national quality measures. NQF board approved it, adopted it, then because of the needs of the NQF of always use the political process, that's what we used at Intermountain. So very, very effectively.

It's what allows me to say that we're missing most of the critical data that we need for clinical management. But it's not just the infrastructure, meaningful use sorts of things. It's the content side and getting the content side right. If you generate those sorts of data, you get accountability data to see how the system performs for free.

If you invest in accountability data, though, it doesn't give you the data you need for improvement. And so that little dichotomy, people don't appreciate it. I'll get 'em to appreciate that and use a rigorous methodology for determining what data are collected within these systems, how it's defined. They tend to be very parsimonious, very, very effective, and very, very different from what people are currently mandating.

John Iglehart: Okay. Bob?

Robert Jesse: Well, I would only respond to Brent in saying that Congress might not understand that definition. *[Laughter]* And I don't mean that to be dismissive, but it's really interesting. And having been on the Hill on many occasions, health care is still about stories. Right? We try and make it – well, we don't try. We drive health care by data, by knowledge, but in the end, it's about an individual story. And it's why I keep coming back to in the end it's quality for an N of one, insight to an N of millions.

And so we need to figure out when we are really trying to get at the large scale, the policy and the legislation that we need to take, US health care needs to go, the right balance between that. And so it's interesting. If you say, "What is the thing that drives major health care decision? Who is the most influential person," it's not who you would think. It's not your spouse or your parents. It's actually your best friend's friend, you know, "My friend had that done, and boy, they did a terrible job, and don't ever go there."

And so we have a whole society that's not – it's not driven on data, per se. It's driven on perception. And health care is so very important that we understand fundamentally the truth, as you say Brent, that making that transition not just to Congress, but to the rest of the public becomes really important . Why is there such a complete lack of interest in – not complete lack, but when you go and look at Hospital Compare, it really didn't have the kind of huge impact the expectations were. We publish all our data, huge amounts of data on public-facing websites, and it just – there's not a lot of activity there because people are still about their own personal reference points, their own personal stories. And we who work in this quality world, in a world of big data need to remember that because, in the end, maybe it's the small data that's the most important thing to drive these big changes.

Marc Triola: I don't work for the government, so I would probably have a lot of questions I would want to ask them. I mean the things that I would advocate for – I'm an idealist. I would advocate for policies that reward transparency and interoperability, that reward sharing of data. If we're talking about big data, no matter how big we are, none of us are gonna be able to do it by ourselves, and we need to think about how to create an environment that really encourages and rewards sharing.

John Iglehart: I don't see any hands out there, but I might be missing it. Yes, sir.

David Atkins: Hi. David Atkins from the Office of Research and Development at the VA. So since I work with Bob, I'll direct this question to Dr. James. So we fund research on health information technology, and we sometimes – our scientific review panels look at something, and they're looking for sort of generalizable insights and they see something that maybe sometimes looks a little too practical or quality improvement. So from your end, in terms of what we know about how to use data towards improvement, what are the generalizable questions that you don't think we've answered yet about how to do it better that would be where we should focus our research? Bob can also weigh in too.

John Iglehart: Did you hear that, Brent?

Brent James: I think I picked up most of it. We use the resulting data structure with a management structure inside Intermountain to continually learn, the learning health care system. Occasionally we use randomized controlled

trial designs. Much more frequently, especially for improvement questions, use quasi-experimental designs. Some of it's just case series, but the amount of that available to us has increased dramatically.

It is useful for translational research in the NIH scheme T4 T5 research. It doesn't address core basic research questions, so we're not able to talk about that at all. But in terms of knowing what happens to our patients, being able to track the impact of, not just a drug or a device, but also the results of a trial. We know that very often when you deploy a trial into clinical practice, the findings of trial, that very often you can't replicate them. They're hard to replicate.

We can show what happens in our hands with that particular therapy and the problems that happen with its execution. That turns out to be a very, very rich and productive learning environment along the way, but it's for a specific class of problems. It doesn't fit outside of that. So it begs the question of what traditionally has been the real role of universities in terms of basic research questions and then bringing those things forward. Does that begin to address your question as best I heard it?

David Atkins: Yeah, I think so. And I'd invite any of the other panelists to weigh in. But I think that is something we've wondered about is using big data sets to validate the question about going from an efficacy to effectiveness and especially to look at subgroups that you can't look at in a randomized trial. To see whether once you have good trial results, do you actually get the same benefits not just in your system but for the individual subgroups within your system that you may have questions about.

Brent James: Yeah. We're able to really drive some serious volume into these things, even just a single big integrated delivery system. I'm not sure how much I have to collaborate with other integrated delivery systems, although, we would pick up a little bit of speed. But for common problems, we get enough data to do clinical effectiveness research very rapidly and quite thoroughly. Has to do with sample size problems. Now, what that relies upon is that integrated data infrastructure organized around specific – well, the way that we do our work – disease treatment processes, really, on the larger part.

But yeah, that's where it really shines is clinical effectiveness research. It also can do some trials too, though. For example, a few years ago we launched a trial of new medications in community-acquired pneumonia. I think we put 5000 patients into the trial across about 3 months. But the reason is we integrated it into our care delivery system. So you can answer those sorts of questions very rapidly as well.

Robert Jesse: I think that's a great point because – well, first of all, a lot of things we do in medicine are – there's no evidence for it anyway. Its evidence-free zones, and we really have the ability, with these large data sets, to go back and start looking at that. Vitamin D is a great example or vitamin E and C. But also, a lot of point-of-care enrollment into research, where you're not taken out into a separate system. Essentially you agree to donate your data and your outcomes based on a randomized decision at the point of starting a therapy, say, and all the rest of the follow up is through the usual health care systems. Provides a huge opportunity to study comparative effectiveness in ways we've never really done before at a very inexpensive model relative to the traditional enrolled in a clinical trial. There's one.

John Iglehart: Thank you. Yeah. We have run out of time. Please join me in thanking the panel.

SESSION 5: ANALYZING PATIENT SAFETY SIGNALS: EHRS, REGISTRIES, AND BEYOND

How are the data collected by regulators and health systems being harnessed to improve patient safety and outcomes? This session explores key examples of how data are being used and describes the rapidly evolving regulatory environment.

Moderator: **Ronni P. Solomon, J.D.,** Executive Vice President and General Counsel, ECRI Institute

Jonathan B. Perlin, M.D., Ph.D., President, Clinical Services and Chief Medical Officer, HCA, Inc.

Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food & Drug Administration

William B. Munier, M.D., M.B.A., Director, Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality

Ronni Solomon: Welcome to our last session and welcome to our panel. How do I get this? Okay, so I know we've talked about a couple of industries other than health care today. Right? We touched on sports – baseball. We touched on transportation – GPS and navigation systems. And I'm gonna touch on another one, and that is the art world. So who can see what this is? Anybody see this picture? What does it look like?

Well, there's what it is. You're looking at sort of a mouth and a lip and a nose area of a wonderful portrait by an artist named Chuck Close. So, I don't know how many of you have seen his work. In fact, I think he's on view at the Smithsonian or the National Gallery and the Hirshhorn. But he paints these fabulous seven by ten foot photos, and when you're up close, those individual cells don't make any sense. They're just individual cells. But when you begin to step back 2 feet, 3 feet, 4 feet, 10 feet, and 20 feet, it all comes to fruition, and you can see the picture.

So, the question that I think our panel is going to address today is, "Can we say the same about our understanding of patient safety signals? How many safety signals do we have to see before things make sense? How many varieties on the theme do we need to see before it makes sense? How much do we need to step back before it makes sense, and how much do we need to aggregate in order to get some good data out of the analysis.

So, with that start, I'd like to turn it over to our first panelist, Dr. Janet Woodcock, and Janet is the director for the Center for Drug Evaluation and Research at the FDA.

Janet Woodcock: Well, good afternoon, and I thank the Institute for inviting me. I'm going to talk about – I'm from the FDA, and so – the Drug Center – so, we're very interested in the safety of drugs once they get on the market. And people have long used claims data, often relatively what we call small datasets rather than big, to try to answer questions about drug safety once drugs are on the market.

And my 18 minutes, I would just want to tell you two things – okay? – in those 18 minutes. So, the first has to do with methods. So, people have academics, and others have developed methods to monitor, because these data are obviously generated for a different purpose, either from claims or electronic health records and so forth. And then we want to repurpose them to answer other questions that we have.

And so, a question that arises is how reliable are these methods that we use? So, there was a collaboration that I was a part of for five years called the OMOP Experiment. That stands for the Observational Medical Outcomes Partnership, or OMOP, and it was a five-year methodologic research program based at FNIH. And we decided we would generate empirical evidence about the performance of the different methods that are used to analyze these data. Generally speaking, you can't just say – I mean you can look at what happens to people – right? – if you give them a different drug or something or like that, but it doesn't necessarily tell you what would happen if they didn't have the drug.

And so to draw causal inferences, you usually have to do some kind of comparison. Right? And so, there are lots of methods to do that. But we don't really understand their performance characteristics in different datasets. In particular, how sensitive they are for identifying a risk and how often they have false positive results. And what we

wanted to do is better understanding of these methods so we could have a systematic and reproducible process that we use observational data, for example, in my case, to make regulatory decisions about different drugs that are on the market.

So, OMOP did a major experiment, and the results of this are published in a supplement to Drug Safety, Vol. 36, Issue 1, which was in October 2013. And we studied four health outcomes of int. So, we picked things that usually happen with drugs a lot. Right? Acute myocardial infarction, acute liver injury, acute renal failure or GI bleeding. All right? And they're sort of defined events. So, they're acute, and they're defined. And we assembled an observational database. We've got 5 different data sources from 150 million-person years, and we also used 16 simulated datasets. And these were primarily claims data, but we used EHR data as well.

And we assembled a reference set of drug-outcome pairs with 399 test cases. So, we got – so, we didn't introduce any new variables. We tried to take known positives – right? – drug-outcome pair, and known negatives. And we did a whole lot of literature review and looking at the drug label and everything to try and get a standard of truth. This is important later because once the results came out, everybody said, "Oh, well, actually, these aren't the standards of truth, but that's kind of revising history. Right? But it is hard to know, because we don't have good data, even on drugs that have been used a very long time, about how often they may actually result in some of these outcomes.

So, anyway, we assembled these controls, and then got seven different standardized methods that are commonly used by academia and the practitioners of the art, such as case control methods, propensity matching methods, and so on. And then because of how this experiment was done in a computer lab, we were able to do many, many permutations. So, we did actually get big data at the end, because we were able to say one of the permutations might be, "How big of an interval do you construct?" And you can construct an ___ on each end of the event. "And how long do you watch before or after an event and so forth?" You can change all these things.

Then we tested the strength of association for all these test cases and these thousands of permutations. All right? And then we asked ourselves, "How reliable are these methods?" And here are the results. So, this is what we long suspected, based on – we'd get observational studies, and then we would – we'd get observational study results, and then people would do randomized trials. And often we would not find, necessarily, the same result in the randomized trial that we found in the observational study.

Some people might say, "Well, that was because of lack of generalized ability in the control trial," and other people would say, "The observational study wasn't right." So, we – this is really important. How predictive are these? Well, they are better than random chance. And we generated the curves for each analysis. And you can trade off, of course, sensitivity specificity, depending on where you set the thresholds – right? – in all these methods.

So, if you decided you wanted a 50 percent sensitivity, you would want to have – you would end up with about 95 percent specificity for acute renal injury; 89 percent for acute liver injury, that turned out to be a hard one; 92 percent for AMI; and 94 percent for GI bleed. But, of course, you can set the sensitivity threshold any way you want, or you can do it the opposite way and find out what the results were.

So, what does this – what else did they find out? Well, in this experiment, self-controlled designs were optimal. They were closest – the curve was closets to the true standard that we had. And there were substantial variability for the same drug-outcome pair across data sources and also by method. So, depending on what method you use, you get a different result, and depending on what data source you were looking at, you could get a different result.

And we also found traditional statistics don't correctly describe the distribution of the results that we found in these, because we were able to look at the distribution results that we got, and where the actual sort of 95 percent confidence limits would be and so forth. And they may generate a lot of statistically positive results that actually aren't – don't correspond with the distribution. And so, we proposed and tested a procedure to empirically adjust the confidence intervals based on using these known outcomes in the database and then proposing how you would set the limits on a real result, basically based on running a bunch of known positives and known negatives. All right?

So, the experiment has gone on, and they're trying to evaluate how to improve the performance of these methods so they can become more reliable. And, of course, we parse out the outcome. We work on each outcome separately. We can get the methods better if you – you can empirically match the method to the question. Again, using a similar set of questions and testing the method performance in those, you can pick the best method and apply it to a new question.

Restricting analysis to a case with sufficient sample size – that would seem to be intuitive, but actually, a lot of people don't necessarily do that – and optimizing the method to the data source. Okay? Because some – these are mainly claims data, but also EHR data. And depending on how they're configured, what kind of information is in there? What kind of odd characteristics they have when method may perform better in one data source than another method.

So, these are empirical results that we have about the actual performance that we can then sort of apply to assessing these results in the real world and how reliable they would be to make regulatory decisions about safety. So, recently OMOP has been transferred to something called IMEDS, which is a safety – drug safety program at the Reagan-Udall Foundation, which is FDA's foundation. It was set up a number of years ago, and their new governance processes and structures, and we hope to integrate this with our Sentinel program, which I'm going to talk about next.

And they recently had a final OMOP symposium. You can go online and look that up for their final results, but we hope to continue and broaden this research, because right now – and I'll say this again in a minute – but these results cannot stand alone usually, unless they're really – there's really an outlier. It's a very large effect. We can't simply rely on these results from observational study.

So, the other program we have is sort of in the opposite pole, which is a Mini-Sentinel system that we have built and are using under contract to look at drug safety. And this is an operational system that is trying to address questions that arise. And I'm going to give you a couple examples. So, do you understand that?

So, this is a distributed system where we did a common data model, and then we do queries. We have standards queries, and we do it beyond the fire – behind the firewall of the various health care systems or data partners that are participating so they can perform the analysis. They simply give us summary results back. So, we are doing this – we don't have a lot of privacy concerns and so forth because we only receive summary results, and we can really get pretty fast answers.

And what kind of answers are we looking for in this system? Okay, I want to give you an example, Dabigatran. This was an anticoagulant that we proved in 2010 to reduce the risk of stroke in people with AFib. And it was based on the RE-LY trial. It was a very large trial. But it found that Dabigatran was superior to prevent strokes in these patients, and there was slightly more GI bleeding with Dabigatran, but less intracranial hemorrhage, which, of course, that's an outcome you really don't want is to have intracranial hemorrhage. Right?

Now, we know, though, that warfarin is so commonly used – okay? – but we know that for emergency room data, this is one of the most common drug-induced severe/serious emergency room visits would be a warfarin bleeding visit. Right? So, why did we get – so, in the first year of marketing with Dabigatran, however, we got greater than 10,000 reports to our spontaneous reporting system, mostly about bleeding. Right? The drug was widely used and adopted. There were over 250 fatal bleeding reports in the U.S. alone that reported to us. We know that means there were more out there.

So, this raised an urgent question. There were calls to pull the drug off the market and so forth and so on. These reports – as general, the reports we get, we call them low quality. I mean there's a high energy of activation. Somebody has to write this up and send it in to us, to our spontaneous reporting system. And, of course, reporting for Dabigatran was much greater than warfarin reporting.

But so what was happening here is a question that we had to urgently answer. Was the post-marketing use, as the previous panel talked about, was it different, and so you're actually getting different outcomes? You know, there was some of that, but this is not what we studied. Were they not being dosed correctly? Were they not – was it in a different patient population? Or was this what we call "stimulated reporting?" In other words, because there was a lot of media interest in this, there was a lot of conversation

about this, it was a new drug, naturally there were warnings from other regulatory agencies about bleeding from this and so forth and so on, and who would send us a report on warfarin? We do get them, but everybody knows that warfarin causes bleeding, and it's like the number one – one of the major causes of admissions from drug-related adverse events. So, we didn't know.

So, the question that we urgently needed to answer: is there really a difference in bleeding rates for Dabigatran compared to warfarin in the post-market setting, which would be in contrast to what we found from that randomized – very large randomized trial that was done. Right?

So, we have a modular program with Mini-Sentinel, and what we did, we got – they got identified new users in the system. So, that was the first part of the query, who were either using warfarin or Dabigatran. Okay? And then they got a claim for GI bleeding or intracranial hemorrhage in the inpatient setting. If you're an outpatient, we really – it wasn't very serious, probably GI bleeding. Okay? And 183 days prior to index prescription you had a diagnosis of AFib, and know whether or not you had dispensing the study drug and no bleeding event. So, we had a window beforehand that you hadn't had these problems. Right?

So, the results, you can see here, what we found was we didn't find an increase in bleeding for Dabigatran. In fact, we found numerically lower – now, this isn't adjusted for a lot of things – all the problems I just talked about with the methods. Okay? So, we can't totally rely on this. We found a much lower number for Dabigatran than we did for warfarin in a fairly large sample size here, which we were able to get very rapidly, 'cause this was a very urgent and important issue to resolve.

Now, there was a lot of limitations, no adjustment for confounding, of course. Now, I would say I'm not sure that's the appropriate thing to do based on the OMOP results. But there was not medical record review to make sure this was all – you know, we didn't have time to do this. Those type of studies usually take a long time. The algorithm hadn't been validated. There was a small number of events. We always are waiting, when we release a new drug for enough users to accrue so that we get all this. And we are doing – and this is one of the great advantages here. We can do a protocol-based assessment, a formal epi-type of study of this, too, and that's ongoing. But the horse is well out of the barn as far as the public concern. So, being able to do this rapid look at the Mini-Sentinel database was very helpful for us.

And so, what we did, we put out a safety communication and we say we looked. We looked at the actual users out here and so forth. And what we found is that the bleeding rates – the actual bleeding rates and the actual use of the drug do not appear to be higher than the bleeding rates associated with the new use of – with the use of warfarin. "New use" meaning initiation of warfarin consistent with observations from the large clinical trial. So, that put this issue somewhat to rest, while we can do more formal investigations of this.

Now, another question we had, we get some – and this is just very quick, so I know I only have 18 minutes of time – that we got a question about the drug olmesartan, which is part of the sartan class. Okay? It's antihypertensive. Okay? And so it was associated with celiac disease, and this would be – this is very unusual, and we thought, "Well, how can that be," and so forth. And so, we just ran a subsequent diagnosis of celiac enteropathy against a whole bunch of these that are on the market. Okay? And this is what we found, the blue being the drug of interest.

So, the regulatory outcome was FDA's warning that a blood pressure drug can cause intestinal problems known as sprue-like enteropathy. And so, we were able to actually confirm, sort of, that that report or the series of reports that we got very rapidly by running this in this Mini-Sentinel database. So – but our conclusion was largely based on the reports we got, the K Series information about Mini-Sentinel assessment was included. So, we are not using this as a stand-alone. With the Dabigatran case, we had a large, randomized, controlled trial, where we found the same thing. Here we had a K Series, and when we duplicated that result in the actual health care system in Mini-Sentinel.

So, what do I – what is the bottom line on using this kind of data for monitoring drug safety? Well, first of all, we definitely need continuing research on the methods used for observational studies. And we need empirical, I believe – continued empirical evaluation of the performance in comparison with randomized results, and we are able to do that. And as one of the previous – a panel just said, we can – you can randomize, within these – once you set up these systems, like Mini-Sentinel, we can randomize within there, or we can do cluster randomization and so forth, and so, there are ways to actually compare the randomized results so we can even generate in the system.

But the methods are likely not reliable for small-effect sizes sort of period right now. That's our conclusion. Using straightforward comparisons, they aren't adjusted, and they aren't elaborate and so forth, but just, "Here's what was seen." Mini-Sentinel is generating valuable information, but observational methods cannot currently stand alone when making causal inferences. Now, they're gonna have to in the future, because we don't enough clinical trial enterprise to answer all the questions we're gonna have to answer. But to really answer these questions in observational databases, we're going to have to improve the methods.

Thank you.

Jonathan Perlin: Well, good afternoon, everybody. It's a privilege to be here. I want to thank Jeff Lerner and ECRI for putting together just a terrific and very timely discussion. Really, share with you a story that has a bit of circle. It took its roots here in the halls of the Institute of Medicine, about how

> we could accelerate the performance of health care and really learn much more effectively and much more efficiently.

We thank Mike McGinnis, a senior scholar here at the Institute, 'cause some – a lot of the ideas were born out of the work at the value and science-driven health care roundtable. And, Ronni, I think you're beginning was very apropos, because the idea of moving from the pixels to creating the picture is really what I want to talk about today in terms of a picture of safety, and picking up a little bit where Janet left off, how we could use the signals from the experience of health care to, in fact, deliver more effective, and more efficient, and safer health care.

And thus, we'll talk about a pragmatic research opportunity that we participated in, in HCI, and this issue of interoperability in health information really as being a door to efficient and effective learning.

So, I'll use the REDUCE MRSA study, which I'll explain momentarily, as really a demonstration of research at scale. And then I want to talk about research at scale, but done entirely in silica or, that is, by computer. In this instance, a registry example, the recent TASTE study, where information was created as an adjunct to care and a dedicated stand-alone registry. And then what I really want to leave with you with is the promise of an ecosystem of possibility from interoperable health information, where information for the sort of resolution of the picture is a byproduct of the care itself and supports a learning health system which really, as the IOM defined in 2007, one that has the capacity to both generate and use evidence in the course of practice.

So, let me tell you a little bit about the REDUCE MRSA study. It really takes its roots in a significant patient-safety issue, and that's the one of health care-associated infections. Sadly, about 1 in 20 patients hospitalized will acquire something they didn't have before they went into the hospital, namely an infection. That amounts to 1.9 million patients, 80,000 paid the ultimate price; that is their life. And society pays a toll as well, $10-$20 billion. MRSA, methicillin-resistant Staph, in addition to other forms of staff, account for about a quarter of those infections. And the very real question was on the table, "What would be the best way, among competing strategies, to prevent not only MRSA, but potentially other health care-associated infections.

The REDUCE MRSA study was pragmatic research; that is to say it was done in the course of routine care and not a dedicated research unit. It's a comparative effectiveness study. It put head to head three competing – quote – best practices to find out what was truly best, and it was cluster randomized by hospital; that is randomization was used, and three strategies were assigned to a third of each hospital.

Those three strategies were one, screen the patients for MRSA and, if positive for MRSA, isolate them. Arm two, screen. If positive, isolate and then decolonize, using a body wash of chlorhexaphene and the purest of nasal ointment. Or three, a novel strategy, which had some promise, which was to decolonize every patient on admission to the intensive care unit.

Let me give you some idea of the scale. This was really a national study, and you can see arm one and arm two and arm three around the country. And let me give you a sense of the degree of enrollment, in that among those 43 hospitals, there were nearly 75,000 patients and over 280,000 patient days. Baseline data were already available in the electronic health record, and the intervention actually occurred only over a period of 18 months.

Overall, arm three significantly outperformed the other arms. In fact, in comparison to all others, you see *P* of .0001 in terms of defining universal decolonization as the strongest signal best strategy. In fact, reducing bloodstream infections – all bloodstream infections from all pathogens by 44 percent. And that's pretty significant, because that's on top of all their known best practices, the bundles that we talk about. The number needed to treat was actually 99. That is to say, for every 99 patients treated, 1 bloodstream infection was avoided, and it fundamentally sets, we believe, a new standard for preventing infection in intensive care.

You see a number of the study partners – and I'm going to come back to the importance of this partnership in just a moment, in terms of what was notable about the study, namely not just the outcomes, which obviously were quite significant, but the methodology. I'm being a little facetious here, but the speed, it didn't take a single institution 43 years or 43 times 1.5 years to answer the questions; it took 18 months.

The implementation wasn't done by a research team; it was done by nurses and infection prevent folks in the course of the routine care as an alternative strategy. Similarly, it didn't occur in a dedicated research unit; it occurred throughout community hospitals and some academic medical centers across the country, all parts of the HCI system. And efficiency was extraordinary, including the supplies, the entire study for 75,000 patients. It cost $3 million. And they contrast that with all ALLHAT, the study for hypertension outcomes involving 42,000 patients, which cost $80 million dollars. So, it efficiently answered real-world questions in real-world environments that generalized real-world situations.

Now, the important part, in terms of big data and learning, what made the study possible? Well, this is where I want to acknowledge the partnership. There is a partnership with public sector, with Agency for Healthcare Research and Quality. You had a sponsor in CDC as part of that learning collaborative, wanting to study the head-to-head comparison of these three strategies.

The host organization – mine – made a commitment to infection prevention and, in fact, already had lower rates of MRSA, based on use of some empirical data from world-wide performance, but really, we begged the question of what was truly best. And we committed some resources to them.

Randomization is often necessary for good research, and indeed, the cluster randomization allowed us a tool to study this in an appropriate way. But really, at the

end of the day, the interconnected, interoperable health information was absolutely critical.

I want to call out a couple of colleagues who are particularly important. There is also an exceptional academic collaboration with Rich Platt at Harvard Pilgrim and the Epicenter's program, and his colleague, now at UCSF, Susan Huang, is the lead on the publication. And this partnership really allowed a novel approach.

Now, as we've written in a commentary that came out from the Institute of Medicine, some of the information-related supports that made this possible were one, the standard information platform. That is to say, across our HCI hospitals, we have the same EHR, and that allowed some transmission of data.

This concept of semantic operability – interoperability is tremendously important. That meant that a sodium here equaled an NA there, or what have you. So, we could keep the meaning intact. Second, we could bring the data together into one repository; that is we could aggregate it. Third, we could normalize non-standard, non-computable data as part of the process. Fourth, we had continuous quality feedback for improvement of the data quality during the process, and we could analyze the data in situ. So, it didn't have to go somewhere else and potentially risk security or transport issues. And that allowed really the safest and most-efficient analytics to occur.

Now, I'm haunted by a terrible and wonderful thought. And that is, what if the study weren't necessary? What if, in fact, the results of REDUCE MRSA, with the strategies compared, were actually already present in the data generated by previous care? What if the trial could have been performed in silica? And what other answers to pressing questions might exist in the collective memory of our health care services?

Well, my point with this diagram is not to ask you to read this, but any trialist here would look at this and say, "Randomized control trial." What's unique about it is that it was the recently-published – I think the date up there, October 24 – very recently-published study was done in silica in a registry.

Now, admittedly, there was some randomization of patients before, but basically, the results were already there in 12,000 patients available from Sweden and Denmark, 7,300 approximately were enrolled into 2 groups. One who had percutaneous intervention with the aspiration or essentially sucking out the clot before the stent was put in – put it in technical terms – or a traditional stenting procedure. And look at the cost of this study – $300,000.00. And the answer was, is that what sounds like a pretty aggressive intervention, that thrombus aspiration, before stent placement, had absolutely no impact on mortality.

So, let's extend to that for something that was done in silica to – in a highly-structured disease registry, which are indeed necessary today to accumulate information and sometimes in very esoteric information that isn't available in the general medical record

– to questions about what sorts of things might be opportunistic that we could learn as electronic health records become more prevalent around our country.

Well, if you look at this graph, we have a lot of use of electronic health records today. In fact, as of December 31, over 50 percent of doctors and 80 percent of hospitals at least participated or met the meaningful use Stage 1 criteria. Translation: they're using electronic health records a lot, increasingly for order entry, but lots of lab data. And that's great, but are we learning? Are we tapping into that collective memory?

Well, I want to update those numbers. In fact, I wish I could have been here in the earlier part of the day, but I had the privilege of chairing at the Health IT Standards Committee. So, I'm gonna share with you some data that were released this morning. In fact, the current rates of electronic health record use meeting Stage 1 requirements among hospitals is actually up to 84 percent now. Quite significant.

And you see that really it's quite similar rates of uptake of electronic health record among small, medium, large hospitals; rural hospitals; and critical access hospitals. And for those of you who look at this, you can see some of the big name systems – Epic, MEDITECH, etc. So, there's a lot of use of electronic health records.

Some other data released this morning included those about eligible providers for physician practices. And you see now that the rate meeting Stage 1 is up to 69 percent. And you can see that the similar use patterns among both rural and urban – and you see some differences in medical specialties. You see surgeons, primary care, medicine in general, and radiology here, and you see some of the medical fields that are not directly – not necessarily hospital related. One way of saying there's an awful lot of uptake here of information.

Why am I so excited or optimistic about this ecosystem of possibility? Well, this uptake isn't just hospitals using, but hospitals and physician practices using information that has a set of standards that really address the meaning of the information, the structure of information, the security of the information, the services for using that information, and the transport of that information, which is really a requisite for big data. Think about the opportunity of the information that can flow when you have information where words mean the same thing across the environment, there are code sets for values. Dr. Munier will talk about some really important work in regard to all three sort of – all of these areas.

The content structure. What does the message or the payload look like, and the protocols for securely transmitting information between sites, including to repositories for analytics? Well, this is also just out this morning, and I want to share with you. I've given you a link to the website here, ONC-MUSICO, which is actually an acronym for Meaningful Use Standards & Interoperability. And you can look at the different sets of standards which are important in terms of thinking about questions which may be amenable to answering or addressing through big data.

And if you look at any particular relationship – and this is not a static image; it changes dynamically – you can see what sorts of information and what sorts of transport standards govern the use and transmission of that information between different sites. And this really opens up an incredible world of possibility. When I think about health care-related big data, it certainly meets all of the basic criteria of big data, that is, large volume, very heterogeneous, a high variety, and create it extraordinarily fast. And when I think of what's coming to this aggregation of data assets, it's not only information from the electronic health records, but diagnostic and therapeutic technology providing feeds, genomic information being fed in, and importantly, patient and patient consumer device-generated information all potentially aggregating. Part of this morning's discussion was, in fact, "What do you do with information from a fib. that comes in, and how do you relate that?

So, in fact, we are creating the opportunity for an awfully large, potentially valuable dataset that answers some incredibly important questions and help us understand, at a population level, what's generally best. We can understand in terms of a personal level what's categorically best. And as we link to molecular biology, we can understand the relationship of molecule to man to disease, be it host factors or, in the case of infection, the biome of the infection itself.

Well, in point of fact, when I think about recreating the REDUCE MRSA study electronically, it falls in this category. It was a categorical answer to, "What is best for intensive care unit patients in terms of infection prevention?" Oddly enough, we're going from that to the broader case right now, which is really the question of, "What happens for the entire population of hospitalized patients?" We're recreating something that's very similar, again, with Rich Platt and Susan Huang, CDC, NIH in this instance, and AHRQ and other academic partners in a study called ABATE. As of now, we have 55 HCA hospitals enrolled, and we anticipate approximately 400,000 patients in answering this question. And, of course, we'll be looking, in the future, to linking both the molecular biology of patients and infecting organisms to the outcomes as well to answer these sorts of important questions at a level that really is the definition of precision medicine.

So, let me close with this; this is an extraordinary moment. We're on the cusp of a transition, if you will, from Web 1.0 to Web 2.0. We're at a point of transition from the creation of big data to the opportunity for use of big data. And when you think about this – this is a graphic that's borrowed from the National Research Council – we have the opportunity to use these data to inform care, and care to continuously cycle back in a virtual cycle, building the dataset, making it more robust. The information in this knowledge base is not only the – or not only those things that are the byproduct of the health record, but you can think of demographic data. You're thinking of patients with COPD or asthma; you can think of meterologic data. It is the ultimate mashup that allows the informing for better, safer, more effective, more efficient care, and a platform for an accelerated learning proposition and a learning health system.

And so, I hope this is tantalizing in terms of demonstrating a promise for increasingly powerful and efficient pragmatic research; that is research conducted as an edge onto the care itself. And it begs multiple questions about how patients, and payers, and policy-makers, and providers – in fact, really looking out here, the constitution of this audience –might interact to really accelerate discovery and the improvement of health care, including importantly around safety.

Thank you very much.

***William Munier*:** Thank you very much, Ronni, and thanks also to Jeff Lerner for inviting me here. I've been able to come to the last session and, of course, this one, and I must say, I think it's the most erudite discussion that I've heard on big data to date and very exciting. I'm hoping we don't take too much of a downturn with this last session today, but in any case, I did have an inspiration when I was hearing Jonathan talking about in silica, a term that I haven't heard before.

And I thought I'd help you integrate the results of the conference today – the last two sessions anyway – and the fact that it struck me from listening to Brent James at Intermountain and the presentation from Bob Jesse at the VA, and then Jonathan's from HCA, that if the three institutions – Intermountain, VA, and HCA – had fully – in the future, fully integrate the common formats as you're about to hear them this afternoon, then, with the touch of a button, because of in silica data, Janet Woodcock could have answered her questions about the warfarin versus the newer drug *[snaps fingers]* without any additional data immediately. That is in the future, but it's definitely very much possible.

So, what I thought I'd talk about this afternoon is just a couple of observations on big data and EHR, the common formats in general, and then two applications of them, and what the future challenges are, which is very much the same now as Jonathan ended up with his – at the end of his presentation.

And the first is that, while the presentations you've heard today are very erudite, and they deal with big systems that are actually doing incredibly exciting things, there are a lot of misconceptions about the electronic health record, what it can and can't do, and big data and what it can and can't do. And I think Brent James had a comment on that, on a big eastern institution that created a big data warehouse, and the value of that data.

And the thing about it is that the transformation of clinical information from paper form to electronic, whether it's an electronic health record or a data warehouse, whatever, has been painfully slow. And the great promise that has been offered, you're seeing glimpses of it, from what you heard today, but that isn't the general, run-of-the-mill experience across the country. And the electronic record, in particular, has not delivered the promise so far that we expect of it. That doesn't mean that it won't.

One wag that I heard a number of years ago said that health care isn't rocket science; it's more complicated.

And I think that's true. I think delivering health care is one of the most complicated endeavors that human beings do. For one thing, we're not making patients. They come already, and they're somewhat of a black box.

And so, the idea of representing what we do in electronic form is a very complicated one. And if records and big data are going to work, the job that has to be done is that the structuring of clinical concepts – which really isn't a computer's job; it's a human being's job – has to be done first. And I love that thing with the pixels that Ronni did at the beginning, because I would submit that you actually need to define the pixels as best you can. And then when you see the big picture, you can actually go back and refine the pixels and make them even better, so the big picture looks even better. And those pixels are clinical definitions.

And just to throw out one random example, instead of just putting symptoms and things – physical findings, etcetera, lab values – into the computer, at some point we're going to have a definition for what an acute abdomen is, and it's going to be the same everywhere, 'cause it'll get refined over time. But nobody has done that yet, and that's not in the electronic records. So, I think it's gonna take a very long time to fulfill the promise that we – the electronic representation of clinical data, whether in a medical record or a warehouse or a registry or what have you.

So, let's talk about the common formats. And the reason that I want to do that is because this whole topic is supposed to be about patient safety and what we are trying to do with the knowledge engineering behind patient safety. So, when I say to fully profit from using clinical information represented electronically for the power of safety and quality, what we've done with the common formats, they don't address quality; they just address safety, not harming the patient. But we are spending all of our time on the knowledge engineering. And after that is done, the people computerize the results of what we've done, but the knowledge engineering is the hard part.

Just very quickly, just so you know what the common formats are, they were authorized by the Patient Safety Act, which was passed in – Patient Safety and Quality Improvement Act of 2005. That Act created PSOs and – recognizing that patient safety organizations, which were going to deliberate on quality and safety, couldn't aggregate data unless everybody kept track of things the same way – authorized our agency to promulgate common formats for all of quality and safety in all health care settings if delivered by a licensed practitioner in one of the 50 states or U.S. territories. Now, that's a very, very, all-encompassing job.

So, we started out with patient safety in hospitals, but ultimately, that's what we're authorized to do. I would say, however, that the formats and their use, it's a little more complicated than this. But at the bottom – the bottom line is that they are now

voluntary, so we have to – we have to essentially get people to use them by demonstrating that they're the best possible way to do – to capture patient safety events.

I believe that they are the only national patient safety reporting scheme that's designed to meet all the following four goals. First is to support local quality and safety improvement. This is not a national reporting system where we sort of selfishly say, "This is what we want to gather together in the federal government." They are designed to support quality improvement in the local institution. If you think about it, the only place that quality or safety can be improved is in the local institution: a doctor's office, a hospital, a nursing home. Our CDC, FDA – we can't actually improve quality. We can facilitate the improvement, but people practicing medicine, nursing, and whatever, who are doing it one way on Friday, have to do it a different way on Monday if the care's actually going to improve. So, we started out by designing the common formats to support local quality and safety improvement.

Second of all, we want to provide information on harm from all causes. We don't want just – many people have laid out a list of things, patient safety events, that they suggest you collect information on, and that's all well and good, but we want to make sure that we collect information on harm from all causes.

The Office of the Inspector General did an in-depth study a couple of years ago of adverse events and found out that roughly 50 percent of them didn't make anybody's list. They were the kind of one-off things that went wrong. So, we wanted to be able to capture everything.

We wanted to allow comparisons over time and among different providers, and we also have an ultimate goal of having the end user able to collect information once and supply it to whomever needs it. And this is the harmonization of data, which means everybody would be defining adverse events the same way. And it's the point that's been made by several of the panelists today, is that ultimately you want people recording information, in the process of delivery of care, that will then be used subsequently without additional data collection burden. And it's not quite that simple, but it's a very, very important concept. So, we've designed the common formats to decrease data collection burden eventually.

So, we started out with common formats for event reporting, and that means that they apply. These are the event-reporting systems that hospitals have, where it's not in the medical record. You report into a system. Hospitals are required to have these to be accredited and reimbursed by CMS. So, we collect incidents, near misses, and unsafe conditions. These are the general kinds of categories, and I'd like to have more time to go into this, but we really don't today.

So, I need to move on quickly, but these are the common variety types of adverse events: venous thromboembolism, health care-associated infections, falls, etcetera. But we modularize it so we can pick up many nuances of these. And if you watch the

bottom one, all others – it should be turning yellow – all others are the place where we can pick up information on things that don't fall into a major category.

Now, how do we do that? Well, we modularize it, and we standardize information on all event types. So, the event, no matter what type it is, the information on the patient – say their location in the hospital, the level of harm – is standardized regardless of the type of adverse events.

The way we're organized now, sometimes, there are adverse event reporting systems that are organized around the type of adverse event. And we would like to get away from that and standardize reporting across all events. Then if there is a specific adverse event, such as a medication error, there's a module for that, which is additive to the other ones. And let's say a device malfunctions and gives too much medication, we have a device module that would be invoked in addition.

We also allow collection of narrative, because we want – again, we want to serve the local institution and narrative is extremely useful at the local level if you're looking at an adverse event. And we also contemplate that people will add their own questions, and we think that's fine, and we know that's going on right now. Big organizations like UHC and ECRI itself has programmed the common formats, and has kept, or retained, or added their own questions.

Now, one of the things to think about is if – let's say a hospital's using the common formats. A patient has an adverse event. They have – they get an overdose of a drug because of a device that fails. They can print out a summary, which is not the answers and the questions that were asked. It's a condensed, clinically relevant summary that reproduces all the information that we have from all those different modules. But then you can go in and query the computer and get – ask it on a modular basis, so you can get an aggregate report of all the patients that had a medication adverse event and get information on how you're doing – or what you're doing that's causing medication adverse events or device adverse events. So, you can turn it either way.

Now, I mentioned that these are voluntary. How did we have the temerity to think we could issue common formats and everybody would use them? That's actually a good question. We do hope that they work better than anything else, and we hope to – it's a program of attraction not compulsion I guess is the simplest way to say it. But now, after working on it for over seven years, these institutions listed have begun to mention this: The Institute of Medicine Report, Office of the Inspector General. We've worked with FDA for two years to align with the MedSun system. We're not quite there yet, but we're close. We're working with ONC on meaningful use definitions, based on the common format. So, we are beginning to get traction. CMS is educating their surveyors to look for the common formats.

So, let's see – yes, I wanted to move now, with just a break here. Those are common formats for event reporting, supporting the systems and hospitals that are used to report adverse events and that are external to the medical record. The problem with adverse

event reporting systems is that they tend to be, with few exceptions – with a few exceptions, they tend to be systems that collect numerators and not denominators. So, you don't have a way of establishing rates.

So, we are transforming the common formats into a retrospective surveillance system. And what that means is that the concurrent common formats for event reporting contain information that's in an electronic or a paper record and more. They don't have denominators. When I say "and more," event reporting systems are used to put information that for – if no other reason, for purposes of medical liability – you don't want in the medical record. That's what's protected under peer view statutes, including the national one, which creates PSOs, but also state protections.

The formats are now being adapted to be used as a retrospective system, which will include denominators, will generate rates, but we have to let go of near misses and unsafe conditions, which are collected in the event reporting system. And there's a tremendous amount of learning from those. So, it's not one system or the other. They really, ideally, would be used in conjunction with each other.

Also, these systems are based on retrospective audit of charts. And one of the previous presentations made the fact that we can't afford to collect information that way anymore. I'd certainly agree. If you could pull all of this out of an electronic record, it would be great. It's just that it looks like, for at least the federal government's purposes, where we audit Medicare charts, and for many hospitals, they aren't able to do that yet, and I think it's still a ways off.

We currently – we currently have a surveillance system in place called the Medicare Patient Safety Monitoring System. It's a retrospective chart audit. Has 21 very important adverse events, including health care-associated infections, falls, pressure ulcers, VTE. It's now being used to track the progress and the partnership for patients. It was built over ten years ago. It's really quite a good system, but it only gets these 21 adverse events. So, we're updating it, and it's – the main reason that we're building a surveillance system is to update this one, but we're generating or we're making the system so that it could be used by hospitals.

Let's see, another difference that I wanted just to mention briefly is that event reporting systems are used by patient safety professionals during a patient stay. So, you have the human brain involved, and you can have things that are more sophisticated that are entered in and judgments that are made. The retrospective surveillance system is done by abstractors who are entering data at least 30 days after the patient's been discharged. So, at that point you really don't want judgment; you want the – you want the questions that are asked to be extremely objective, so that you don't have problems with inter-rater reliability. And what all of that boils down to is that the systems end up hopefully being clinically harmonious, but actually being quite different.

So, surveillance common formats will not be able to address many of the event-reporting common formats elements, such as the majority of medication errors, which

are usually caught in the near-miss stage and something like wrong-patient surgery. Nobody ever writes in the chart that somebody got an operation that was intended for somebody else. So, you have to pick that up in different ways.

However, the surveillance formats are not really a step down from the event reporting formats; they're different. So, some clinical items are the same, such as an error in using a device, is found in both of them. But overdose or underdose – which is something for medications, it's reported in the event reportings formats – can't really be picked up 'cause people rarely write that in charts. So, we have to pick it up by asking very specific questions. For instance heparin, which is a popular example today, detected in surveillance by clinical manifestations of a PTT greater than 100 seconds, or administration of heparin antagonists.

So, in summary, the surveillance formats will allow collection of comparable performance data over time and across settings. So, we can generate adverse event rates with them. We can trend performance over time. We can establish local PSO and national means, and we can benchmark among different institutions.

So, to get to some of the points that Jonathan was making about the challenge that we have coming ahead, the clinical representation of patient safety events really needs to be carried through at three levels. One is adverse event reporting. The second is surveillance, and the third is the electronic health record, which is not a surveillance system in the sense of medical record audit, but actually defining the code that the electronic health record vendors would program in.

And when you get to such a time as all of the vendors are using the same definitions, the surveillance could be done automatically. The adverse event reporting is still gonna be separate. It's gonna be additional because there's information that isn't in the health record. But in addition to this three layers of – currently three layers where you need to harmonize definitions for adverse events, you also have all the electronic vocabularies packaging of information – SNOMED and LOINC for vocabularies; HL7, CDA for the boxcars that move information; and then you have all the ad hoc systems that do all of this that people have done for their individual electronic health record. I know CCH IT for ONC has certified over 2,000 health records, and they all have different interfaces and different ways of handling these issues.

There also are a multiplicity of parties and interests. So, we have CMS with multiple patient safety requirements for reporting. You have CDC's NHSN for HAIs; FDA's MedSun and MedWatch for devices; the NQF's serious reportable events, etcetera, etcetera. If we're gonna harmonize so that we can enter data once into the medical record and report out these events, all of these different parties have to get harmonized. So, I guess I don't have to elaborate on how difficult that is, how much investment people have in the way they're doing things, and what it's gonna take to ultimately triangulate on getting to where we want to go.

I would just close by saying clinical and electronic definitions must be consistent throughout all software applications and reporting levels and be interoperable, where appropriate, and different only when the difference is for a good reason. Core systems need to operate in institutions delivering care so that all of the information for reporting and patient safety, and ultimately quality as well, need to be reported at the institutional level, and all other reporting derived from that.

And finally, the reporting burden needs to be only as heavy as justified by the value of the information collected. Even when it's put into the medical record the first time for purposes of delivering care, no information should be entered if it isn't being used either in the delivery care or the measurement of quality. I would submit to you that there is a lot of information that third parties ask to have collected right now that goes into a database, and one or both of two things happen. One is you never see it again, and the second is that it's not of any value to you. One or the other.

So, I would just like to say, finally, that numbers are very important at AHRQ. We want to make sure that we do everything right and we're careful about everything. And it's illustrated by this sign that I found.

Ronni Solomon: So as people gather to ask questions, I love that new _____ sign. Numbers really matter, don't they? Just a comment. It seemed as though harmonization and standardization were a theme that came out in many of these presentations. And in order to do aggregation, you really do need to harmonize and standardize, and it's a funny thing.

If you looked at that Chuck Close painting and those individual cells, if he didn't use the same colors and the same kinds of brush strokes and the same texture, it wouldn't have made sense when you stand back. So even he had a common format. But, Bill, you said something at the beginning of your presentation, and it was about the promise of the electronic health record. And I guess my question to each of you is how likely and how close do you think we are to really getting proactive patient safety signals out of the EHR? Does the EHR have enough in there to give us enough patient safety data to be able to get actionable information?

William Munier: Well, I definitely have an opinion on that. Jonathan, who's more directly on the front lines now, will I'm sure have one as well. But I actually think we're further away than I wish we were from that. Because, at least the common formats, is we're now in the process, as I've just explained, of developing surveillance formats which are based on the medical record and what's in the medical record. When we get those finished, the possibility of transporting from the medical record into the surveillance

formats will be much more of a match.

But the event reporting formats, which are finished for hospital now, we version them. So we update them, but there is – version 1.2 is out there now, and it fully describes the formats for event reporting. As I saw, we went through, actually, and looked at all of the data elements that were in the common formats and said to ourselves, "How many of those would be in an electronic medical record?" And we found that probably fewer than a third of them would actually be in the record. A lot of 'em dealt with near misses, some with unsafe conditions.

So some of 'em dealt with things that dealt with an incident that would be reported in the medical record, but the additional detail in the formats probably would just go into the event reporting system and not the record. So there was a minority of information that could be found. You then have the additional problem that each medical record has defined its own interface. Even if they use an Oracle database, they've programmed it differently. They've defined the clinical events differently. Some of 'em are in free text, so if it's in free text, you can't put it into a defined field. So I think that the promise of being able to export into both the surveillance and an event reporting system and then have people complete the event reporting system with additional data is there, but I think it's largely in the future.

Jonathan Perlin: I think Bill and I are looking at this same problem but different angles. I'm gonna take the angle of the workflow of the provider who wants to avoid a bad outcome. So what Bill has just described is the challenge of making sure that the different signals in the data add up to the same answer. If you think about it, that's the plane that crashed. What you want to know are the causative factors.

And if you have a number of those causative factors, then you can actually offer a warning if you have the workflow possible to say, "Hey, doctor, nurse, pharmacist, these are potentially problematic conditions. Do you want to check your altitude?" And that's why I'm optimistic. Now, we need to be able to deliver it into the workflow, and we're not totally there in terms of the electronic health record.

But why I am optimistic is that we've established much of the groundwork to be able to do that and real exciting conversations going on about roles that could be externalized to these big iron systems and help to support that workflow. Just one additional comment. I think that we need to have some degree of flexibility in the way that we structure data, even though we end up needing to be standardized or at least normalized. Because we need the capacity not only the answer the questions that we know to

ask, but really leave open the possibility to answer questions that we haven't thought of yet.

Janet Woodcock: I think that the answer is yes and no. I think, obviously, there's some questions we can answer now, all right, based on very primate electronic health records that are out there. There are questions that can be addressed and answered, and there are algorithms that can be built in to improve safety too and improve decision support for the physicians too, so those things are very good. I think that – I agree with what the previous panelists said about – and you said, I think – the clinical concept has to be better represented and harmonized.

For example, we're very interested – it turns out that a lot of the rare adverse events to drugs, okay, they're driven by your HLA genotype. You may have an allele, and that allele goes along. It's a rare allele in your HLA system, which is your immune system. Okay. And you go along and all of a sudden you encounter a drug and actually you get liver failure or your skin peels off or whatever because you thought that was – that caused an autoimmune reaction in you. It triggered a reaction in you but not anybody else. Perfectly safe for everyone else.

And we've labeled some drugs like that. But we're working with Consortium, who's trying to identify these. But they had to figure out, like for Stevens-Johnson Syndrome and TENs, which is where your skin really loses it, shall we say. There was no common definition. They had to have a conference of dermatologists and dermatopathologists, and they had to develop the definitions, a phenotype of these reactions so that then they could go into their medical record and identify whether or not people had them and then match 'em up with genotypes so we can figure out what genotype causes what.

And I think even at a very primitive level, clinical concepts right now are not well represented in the health record. So I think we can answer – and the interoperability eliminates your effect size, how much you can – you don't have a very big – you can't do huge searches unless you use a common data model or something like that like we're doing in Sentinel to converge everything or harmonize the data. So I think – but you can answer simple questions, and I think over the years what we'll see is a gradually improving in that as people see the utility of it. 'Cause that's really will drive people to use this, if they get information back that helps them take care of their patients and will motivate people to do better.

William Munier: Ronni, I wanted to react to something that Jonathan said 'cause he raised a really important issue I'd like to at least offer my view on. And what he really brought up was real-time, essentially, decision support or whatever

you want to call it, alerting practitioners when something's about to go wrong. And that's tremendously important, obviously, and something we can do with an electronic record we can't do with a paper record. I wanted to make one point, though, is that sometimes people think that that will replace retrospective analysis or data. And I just want to make the point that, for two reasons, it won't.

One is big data and population-based analysis, which you can only do when you have a lot of cases. And so the real-time decision support is never going to replace analysis. The other thing is it's important that the two work in concept because everybody knows about the whole alert fatigue and the fact that physicians turn off the drug reminders and all the rest of that right now. And all we need is a whole bunch of brilliant computer scientists putting all kinds of things, alerting practitioners to everything under the sun, which is not what you were implying, I know.

But the way you can inform that to make sure you only use that where it's really necessary is the retrospective analysis of large populations of data, and you can find out some things. You can analyze retrospectively, put change processes in place, and they go away as a problem. Some are – they don't respond, and that's where you need to put the concurrent things and intervene in the care process. But you can use the two things together to make each other smarter.

Jonathan Perlin: That was really the point, I agree with you, of the last slide, that interplay between the two because it's really those analytics that inform the decision support. And it's really the use of the system that creates the utility or the capacity for the analytics.

Ronni Solomon: Am I on? I'm on. Okay. So talking about analytics, what are your thoughts about how many signals and how much data we need in order to really get something out of information. And I have my own thoughts about this 'cause we're responsible for looking at millions of near misses and adverse events. And sometimes I think an N of one might be enough. I mean if something is that obvious, maybe it's just about small data and it's not about big data. If you have such confusingly similar packaging that you know that it's leading people to make mistakes, how many mistakes do you need to hear about before you try to make change? Because this isn't just about doing analytics. It's about the changes that you have to make from the learnings that you get from the analytics.

Jonathan Perlin: You've asked a great question about evidence. And the question of some things being just things that we need to do, I think was well demonstrated

in the *BMJ* article, a non-randomized trial of freefall from planes without parachute. And obviously, as with similarly labeled potassium and sodium, you don't need to do a study to see if they make the decision, as we did in VA in the past days, just to pull the potassium, which is potentially fatal if confused with the sodium. On the other hand, what's intriguing to me about the power of big analytics, it's not only the hypothesis-driven research, which is the result often times of intuition of prior evidence, it's the capacity for information sciences to evaluate relationships that aren't necessarily intuitive.

And we as humans aren't terribly good about picking up things that we don't believe to be related. Let me give you an example. When I trained in medical school, which wasn't that all that long ago, we thought of lung cancer in terms of whether it was cells that look like a particular type. Today we don't care.

It's the molecular biology that really determines your treatment. In fact, the molecular biology of lung cancer may have greater similarity to an immune disease of the kidney and degenerative bone disease because they share a common genetic frame. And those aren't things that are intuitive, and that to me, Ronni, is where the opportunity for some things that we need to take on the basis of good judgment. Some things that are hypothesis driven and some things that are non-intuitive relationships really offer novel insight or are tantalizing about this future.

Ronni Solomon: I see that we have a question from the audience. Please.

Rory Jaffe: Yes. Rory Jafee, California Hospital Patient Safety Organization. Some interesting talk about getting from what we currently have in our records as well as collecting different information to be able to better understand our patients. Part of our problem is that we get what we pay for, and what we pay for right now is useless data in a lot of cases. As a physician, you know the E and M codes are based upon documenting that which is of no benefit to the patient in the future. Are we gonna be able to get to the point where we collect good data for tracking the care of the patient and the safety of the patient in real time? Are we gonna get the instant data that we're trying to get with all these common formats if we continue with the same rewarding of all this other effort that isn't improving health care?

William Munier: It sounds like that question almost answers itself in the fact that I at least share the goal that you implied with your question. And I think I said it at the end of my thing, we shouldn't collect a single datum that isn't useful in either delivering care or improving quality and safety. And we do a lot of that right now. One of the problems, and Ronni, it ties back to your

question about what's enough. I don't know that there's a number, but what I do know is that one way to start out is to say, "Let's look at the high priority things first."

If you ask experts in any field to say what do they need to study their problem, they will give you a list that will take ten years to collect. And then if you do that for every expert in every area, you will have a list that – basically you're beyond research studies. You're into something just wasting an enormous amount of time. So the real judgment is trying to weigh what the experts tell you is absolutely critical with what is something that's feasible to collect and balancing that and letting the use of the data and whether it helps in improving care or not to be the ultimate arbiter. And I also think you have to look at every individual case where something really goes wrong.

I don't think you can – that's the answer to your question. Then I guess the last thing I'd say is that, to Rory's point and everything else we've been talking about, common sense is really important in this. Ultimately computers can't do it all. Somebody has to sit back and say, "Why are we doing this?"

Ronni Solomon: I think when it comes to patient safety, it's not just a matter of what's going wrong. It's why it's going wrong. And oftentimes you can't necessarily grab data from, let's say, an EHR, on why. It goes back to this morning's point about the real work is about redesigning the processes in order to make the safety improvements. I think we have time for one more question.

Herman Rhee: Herman Rhee, Health Research International. Dr. Perlin, you present an excellent case for the Methicillin-resistant Staphylococcus aureus, which I really appreciate that. But we have a real problem with the health care-associated infection, of course. But I think, Dr. Woodcock, you know better than I do. You play an important role for the initiation of the Qualified Infectious Disease Product Designation.

And with an extension of five-year exclusivity and with the priority and fast track designation, I think you did all you can do. But our industry is reluctant ___ ___ _____, of course, because of cost. But at least the government organization like NIH and other business organization do what they can do and what we can expect. I'm not sure this was right question, but at this moment, the people, patient died because the multi-drug resistant bacteria is attack. It's just helpless.

Janet Woodcock: Well, I think changing the care process. I mean at one swoop, that study reduced more infections, actually prevented them probably as those techniques are adopted than approval of new antibiotics might do. So that's – using these records to improve care is extraordinarily important in keeping people safe from these multi-drug resistant infections. And there's probably a lot that can be done, and the next study we may find out. As far as FDA, we are very interested in this concept of limited approvals. Again, that would mean that the health care system would have to cooperate with us and not use these drugs in situations that are not warranted. But we have been talking about this concept quite a bit, and so I'll turn it over.

Jonathan Perlin: That's a terrific lead in because the concept of limited approval would mean that a trial or a capacity for learning like this would really allow either validation of the area in which the drug is approved for and limited to that and potentially extension. Those sorts of data sets, I think, are such a powerful platform for discovery. For example, it was World Sepsis Day about a month ago, and the senate Health, Education, Labor, and Pension Committee held hearings on what could be done to understand or accelerate the learning around sepsis. And sepsis is the third highest cause of death in American hospitals.

Not everyone with an infection gets sepsis, but everyone with sepsis has had an infection. And right now the Survive Sepsis campaign is based on identifying markers of really sepsis that's fulminating, becoming very severe. Imagine if you could use these data to turn back time and find out what are the common denominators. I mention this because there's a direct analogue to you question about antibiotic resistance. There's the opportunity, not only for the support of new drugs, but really the insight into the overuse of the drugs that we have that's leading to that antibiotic resistance.

I'm excited about, not only the real-time decision support, but the near real-time decision support that would allow us to really automate the process of looking at the culture insensitivity and the drugs, the antibiotics that a patient is on. And if they're on too broad spectrum, really using that as, not necessarily immediate intervention, but a pretty close to immediate intervention to help this challenging issue of antibiotic resistance. So I think there are a number of use cases that would support the more expeditious delivery of new drugs, the extension of uses. Frankly, the prevention of uses where a drug doesn't prove to be validated in the area, and I can give some examples of that. Really preserving the integrity of some of the drugs that we already have and preventing, actually, even more dangerous disease conditions like sepsis.

William Munier: I had just one comment on that. I forgot to thank Jonathan for spending time of the MRSA study, the reduce MRSA study, since AHRQ was the major funder of that study. And just to this point of multi-drug resistant organisms. The findings were very exciting, but we're interested in asking a couple of questions with further studies. One of them being what the relative cost is, which probably is secondary if one turns, as it has, turned out to be much more effective, but we would like to have figures on that. And the second one is whether it does lead to more multi-drug resistant organisms or not.

Jonathan Perlin: Those are two terrific questions, and funny you should ask. The questions are relative cost. When you think about screening in isolation, isolating a patient with barrier precautions to a reserved room with laminar flow, etcetera, etcetera, is hugely expensive. Not only that, when you have critically ill patients deprived of the signals about day and night, isolation takes a human toll as well. So first, the cost is much less _____ _____ a process of screening in isolation.

Second, there are states that still have policy that requires screening. And the study, I think, pretty conclusively demonstrated that this approach is better than screening, so that policy is obsolete. That process of screening is itself expensive, and the cost of this study where the supply is used are actually less than the cost of screening. So that's answered as well.

Third, to be responsible in the conduct of the study, we can report that there are no clinical isolates that have come back positive or resistant to mupirocin or chlorhexidine. The chlorhexidine is a theoretical concern. Mupuricin's not been reported resistance in decolonization. On the other hand, the very real or the very present problem of death from health care-associated infections does exist, so we're tracking that. And both of those are the sorts of studies that we want to do, not only in vivo, but track them in silica and validate that capacity for _____. And thanks to AHRQ for the significant support.

Ronni Solomon: We have one person who's been waiting patiently to ask a question. And I habitually set my clock fast, so I hope I've done that here, and I'd say we'll take one more.

Diana Zuckerman: Thanks. I'll try to be brief. Diana Zuckerman, president of the National Research Center for Women and Families. I was at the OMOP meeting last week on big data, which was very interesting. And one of the issues that was raised was the difficulty of – the differences in results depending on how different population groups were defined. For example, they were

looking at – when they looked at smoking cessation drugs, they had three very reasonable definitions of who were the patients taking them. And depending on which definition they used, the results were completely different. And between that and other issues of difficulty of defining a patient visit, I mean even very – what you would think were simple matters. So I guess my question to anybody who would like to answer it is what efforts are being made to try, through the federal agencies, to try to work with the electronic health records, people who develop them, and sell them to better – to try to better define simple terms?

Jonathan Perlin: I was hoping to turf that to my federal colleagues. But in point of fact, I serve the role as chair of the Health IT Standards Committee which serves the Office of National Coordinator for Health IT and Department of Health and Human Services and working with federal agencies: FDA, AHRQ, and all of the different agencies of HHS with input from private sector. It's really under the Federal Advisory Act, so it's really a very open and democratic process to actually define standards. Because, in a sense, harmonization is a term of art.

To be able to have interoperability, the pipes can't just come close. They really have to intersect for full flow. And we're at an early stage of that, so we're getting a fundamental set of standards that get to the points that Bill and Janet have made so eloquently about meaning that's preserved across sites. That being the content, the vocabulary, the value sets so that what are permissible ranges for that. How we handle that data to transport it. How we protect it to make sure it's secure and that patient information remains private, and how we create a set of standardized services to do all of the things that we hope to do.

So that's part of a large federal process. The other reality, though, is that there's a great cauldron of innovation. And that's everything outside of that process, hopefully accelerated by this process because it does give cues. But those are the two areas where some of those standards are being defined in addition to work, specifically common format, as an example in AHRQ and that OMOP activities and others in terms of drug surveillance at FDA.

Ronni Solomon: Well, please join me in giving a warm thanks to our panelists.

Jeffrey Lerner: So thank you very much to the panel. You were great. And that's really quite a critical issue. I will give you a very short wrap up in line with my very long speeches throughout the day. This is where we are, going around the circle. We've gone through five. Tomorrow we got through the final three.

They are very, very important. For those of you weren't here in the morning, you'll remember this conference is organized like an edited book. So want to know how it ends? You need to be here tomorrow. But we want to, again, try to start on time, and we want to thank you for being a terrific audience. We'll see you tomorrow. And those of you who are speakers, by the way, we have a shuttle bus for you. Thank you.

SESSION 6: SEEKING THE LEARNING HEALTHCARE SYSTEM THROUGH NEW PARTNERSHIPS

In order to harness the potential of big data, novel business, research, and learning relationships are emerging between the healthcare delivery and information technology sectors. An example is Optum Labs, a collaboration between the Mayo Clinic and Optum, which aims to improve patient care by mining data from 110 million claims records. Another is WellPoint's partnership with IBM to create the first commercial applications for the IBM Watson technology. This session will consider the drivers and attractors for these collaborations plus how the efforts are structured, bounded, and governed. Specific attention will be given to how these complex alliances are aimed at expanding the capacity for and pace of innovation, citing examples from cancer and cardiovascular research.

Moderator: **Lynn Etheredge,** Consultant, Rapid Learning Project, The George Washington University

Samuel R. Nussbaum, M.D., Executive Vice President, Clinical Health Policy; Chief Medical Officer, WellPoint

Paul Wallace, M.D., Chief Medical Officer and Senior Vice President for Clinical Translation, Optum Labs

Amy P. Abernethy, M.D., Ph.D., Director, Duke Center for Learning Health Care

Lynn Etheredge: Thank you, Jeff. Good morning. Since this is the session on Collaboration in New Partnerships, I thought I would start with just two slides before we turn to the panel. And they're going to deal with an economist's view about first the economics of data sharing, why we collaborate, and why it's such a powerful and exciting strategy.

Let's consider, to warm up our brains, the first case study, first case. If we had 10 institutions, each which put in 100 cases to a database, we'd have a database, a registry of 1,000 cases. And through the miracle of mathematics, every institution, every one of them, gets 900 added cases for a contribution of just 100. So, a return of nine to one. A lot better than Treasury bills these days.

But look what happens if we expand this toward national levels or broader. If we had 100 institutions, and each of them shared 1,000 cases to a registry or database, we'd have a database of 100,000 cases. So, every institution would put in 1,000 cases. They would get back 99,000. That's a return of 99 to 1, and that's much better not only than Treasury's, but just about anything else, and certainly much better than every institution trying to build thousands and thousands of cases by itself. So, to start us off here, we need to recognize that data sharing is a very high-payoff strategy for institutions, and doing more data sharing multiplies the benefits.

Having made that general point, which I think is fundamental, we have to remind ourselves that it's not always easy to do this. These benefits are not automatic. You actually need to know what questions you're trying to answer. You need to structure the databases to have high-quality data that will answer those questions. The data need to be interoperable. And then we need to have research funding and then deal with those sometimes messy issues of governance, oversight, ownership, privacy, and so forth.

Nevertheless, the last five years have seen a number of national-level leaders and pioneers leading the way toward new collaborations in new data sharing, in new ways of using data on very large scales. Collectively, they are beginning to – I would use the word *transform* and *revolutionize* medicine. Everything from accelerating biomedical research in the development of new products and new knowledge to learning what works best for individuals and delivering better care, all of those are being already influenced, and we're just at the beginning.

Let me just highlight a couple of things in each of those areas, just to remind us of just what the early promise looks like. In NIH, the biobanks and large data bases and the BD2K initiatives are paving the way and making possible a new generation of genetic-based medicine, precision diagnostics, and targeted therapeutics.

Michael Lauer's recent piece in *The New England Journal* on the TASTE trial, talking about randomized registry trials, points the way to how efficient research can be if you introduce it into a – do randomized trials in a system that already has the data systems in place.

So, the TASTE trial, they had to add just two elements to the existing Scandinavian data systems: what treatment and informed consent. The total cost was $300,000.00 for the definitive trial - $50.00 per patient compared to tens of millions that would have been spent otherwise, doing that research in the NIH usual systems. So, a savings of 95 percent. The ability to do 100 studies rather than 10 for the same budget is one of the possibilities we're looking at.

In the FDA world, the Mini-Sentinel system is now accessing close to 100 million patient files with 24-hour turnaround – okay? – 3 times a week. In the old system, we weren't doing much on safety studies, but it would have taken five years or more to organize some of those studies. So, 5 years would be 1,500 days. They're doing a turnaround in a day, day-and-a-half time. So, 1,000 to 1 improvement in speed.

And in delivering better care, we heard the dramatic leader potentials of ASCO's CancerLinQ system in the keynote yesterday morning. That is – holds the promise of bringing new cancer therapies, almost in real time, to cancer patients, and it's very exciting leadership.

We also have from CMS a number of initiatives that are using collaborations at a national level – for example in partnership for patients to try to save 60,000 lives over 3 years. So, all in all, lots of exciting possibilities just in the last five years and just the beginning. But there's a lot more that's already going on than what I've just described. A lot more that can and should happen in the future.

So, we'll turn to our panel. They share a number of characteristics I wrote down. One is they're all physicians who understand that while we may ultimately want to impact millions of people, we have to start with physician by physician, patient by patient, decision by decision, and that's how the impact builds. They're all researchers who understand that the only reliable way to make progress in medicine is through evidence and through science, and we need to make sure that our big data turns into rapid, reliable knowledge.

They're all leaders intellectually and in building organizations. And finally, they are all collaborators. They are building partnerships within their companies and across companies. So, we couldn't have a better set of guides to this new world of partnership and data collaborations than our three panelists, and we will start with Sam.

***Sam Nussbaum*:** Good morning. Thank you, Lynn, for the kind introduction for the panel. The frame that I'd like to share with you this morning is one of collaboration with some very specific examples of how we can make a difference in health care delivery. Because all of the discussion around big data and new information isn't going to be as impactful unless we can deliver this information to settings that make a difference for patient care.

Just a word about WellPoint and the reason why we are able to collaborate in the way that we are is that we represent 36 million Americans. We provide health insurance coverage for 36 million Americans and are the number one Medicaid provider, as well as in the commercial sector. In addition, we have a series of wholly-owned subsidiary companies. You can see some of those on the bottom that actually have as their focus using information in an outcomes research.

So, what we do is we process about 550 million claims annually. And it's claims based, so it enables big data capabilities. It can inform care management; can determine real-world outcomes, which we'll talk about in a minute; and it enabled us to be very strong collaborators with FDA and CDC.

Because of new and innovative payment models and provider partnerships, we're able to take and both measure optimization of care, and how information is used. And this is just an array of all of the hospitals, over 1,000 that are in what are called Blue Distinction Centers of Excellence, where they provide better care and service, where we have models of payment that reward quality, safety, and outcomes; 53,000 physicians that get paid in part on quality and outcomes; and now 50 health systems that are involved in accountable care organizations.

This is a framework for enabling the introduction of better data. And in fact, recently we announced for all primary care physicians that we are establishing incentives for providing tools of success. And if you look at the far right of this slide, you'll see the most powerful is the exchange of meaningful information. So, whether it's information to identify high-risk members, or information to fill gaps in care, that's one of the commitments that we've made.

And along the way, we have acquired some companies that enable us to get to that space. So, here's one; it's called resolution health. And what we do here is we combine our real-time pharmacy data and laboratory data along with medical claims and can identify gaps in care using a comprehensive rules engine. By doing this, we can have clear, actionable engagement in messaging with doctors and patients. But we have other capabilities, particularly those that are in the specialty space. So, one of our companies is called AIM, and AIM began as an imaging management company, but today touches diagnostic cardiology, oncology, specialty drugs, sleep medicine. And again, we have 35 million lives served; 12 million of those are WellPoint, but 44 health plans, in addition to WellPoint, are covered. This enables, again, this extraordinarily amount of information to be turned into clinical data.

Through our subsidiary health core, we have collaborated not only with the FDA and CDC, but you can see an array of academic institutions that together we ask the specific questions that are relevant to health care. I'll show you that in a moment, but we're looking at breast cancer care. So, it's whether we're looking at the inequalities in breast cancer care, or how we approach low back pain, or therapies for multiple sclerosis, all of this is available to us.

And it's not only doing the study. In this case, we looked at 172,000 individuals with back pain, and we saw a number of startling outcomes. We saw lots of surgery in the first six weeks, and these were individuals who did not need surgical intervention. They did not have either a nerve root compression or did not have malignancy. This was just a garden variety back pain. And we also saw that care was dependent on the treating physician. But that enabled us to collaborate with others to develop models of care that would work far better.

Here's an example of convening a large number of thought leaders in the care for asthma in children. And no one knew what was optimal therapy. We knew what the standards of care were with the guidelines that are published by professional organizations, but we actually said, "What happens in the real world of care?"

And we found is that a drug that was not even envisioned as a first-line therapy – it's called Montelukast or Singulair – we found out that this drug was more impactful in preventing emergency room visits and hospitalization. So, even though the cost of care, because the cost of the drug at the time was higher, this was an intervention that made a difference in the lives of these children and in their families. And so, we moved this drug to a more preferred tier and made sure that individuals were receiving it. So, there's, again, practical applications of how this works.

And as we look to the new world that you discussed yesterday and we're discussing today – the impact that we can have in Mini-Sentinel, Lynn said, to turn around information within a day; the OMOP program; PCORI's new clinical data research networks – this gives us an environment to identify; adjust for sources of bias, confounding variables; the opportunity to enrich data with complementary sources other than claims; the research designs that include more sophisticated observational designs; and also the speed, this iterative platform, and the capability for much more cost analyses.

Now, with all of this positive going on, we have lots of other issues that can be viewed as being very powerful, but I think they can be viewed as pulling resources away from national efforts. So, we look at the all-payer claims database from a state perspective, and this is a very active area, but increasingly, if we're not collecting the same database, if we're not measuring the same information, if we're not taking the opportunity to collaborate broader than state databases, we're missing an opportunity.

Well, there are other opportunities, and you heard from Larry Norton yesterday about the work that a number of us are doing with IBM and Watson, the super computer that made its mark in *Jeopardy!* initially… But one of the strong advantages of Watson is that it not only can manage large amounts of unstructured data, but it's a new type of computing called "cognitive" computing. Watson thinks like we do. Watson can take information, learn from the experience of a patient, and impact future choices of care. So, it's that ability to learn, to train, and to optimize through its own algorithms that makes it so powerful.

When we couple that the explosion of information and the fact that none of us who are physicians or scientists or caregivers can keep up with this, you have the power of a Watson. And what we're using it for today are two use cases: one with Memorial Sloan Kettering and IBM we're looking in oncology, and you heard about that, but the other is to look at evidence-based medicine. As you know, many health plans have what's called prior authorization or review of care to make sure that it meets the standards of science, the standards of evidence. And today, at WellPoint, for a small number of our medical policies, we're actually using Watson to look at the information that's submitted and guide optimal care.

A few more words in closing and that is that we have so much opportunity going forward. We have the opportunity in the Choosing Wisely campaign that has been led by the American Board of Internal Medicine Foundation and many of the medical specialty societies, with the goal of having physicians engage their patients to make smart and effective care choices to reduce waste.

And it's looking at this information that we, as health plans, can certainly partner to see how often our physicians, following these guidelines and approaches with their own specialty societies, and how much we can impact improved care. So, it's with that framework that I look forward to the talks of our colleagues and engaging all of you in dialogue. We have really – like the opening of *A Tale of Two Cities* – you know, we have the best of times in health care, the worst of times. We've certainly seen some of the worst of times in terms of our – the quality and the lack of affordability of our health care system, and we're working, all of us, on improving access. But the best of times, because we're going to take this large amount of information, collaborate, find out what works in the real world, and ultimately introduce this into clinical practice at a velocity that has not been seen in health care.

Thank you.

Paul Wallace: Thanks, Lynn, and thanks very much to Jeff and ECRI and all your ECRI colleagues. I think it's always fun to have this conference every year, and it's particularly fun to have it being about such an important topic. I think the richness of the discussion yesterday was really something we want to carry forward today and think about not only how do we carry it forward today, but how do we take it home and think about how we leverage it going forward. I think Glenn made a good point that there is this huge potential sitting in front of us about how we can tap into the collective experience of hundreds of thousands of physicians and millions of patients and not lose the data. The economics around that are really important, but I think the opportunity to improve care is really the imperative and the driver.

And yesterday, we – think about and focus actually on this picture. You kinda wonder where the corporate people are when they create these pictures. But this one to me is really interesting, 'cause I think it gets to the metaphor of what we're dealing with. We're really thinking about, "What can we do through data sharing, through knowledge creation, through decision support to give clinicians like these better tools than the object they're holding in their hands right now?"

I think there is also a very important complement to that, though, is that I really am curious about what they're talking about. 'Cause I also – one of my bigger concerns is that our research priorities have not necessarily reflected the needs of the front line, either in terms of where are patients getting stuck, and where are clinicians getting stuck.

So, one of the other opportunities here, as we deal with this interface, the chart, is to realize that the chart also ought to be our window into understanding, "What are the critical issues that we need to confront as a larger health system." So, the learning health care system is not about smart people telling the front line what to do; it's really about, "How do we create more of a collective operation so that we understand the needs of the front line and can translate that into actionable knowledge in a very quick and timely manner?"

So, we've shared that concern, but also that opportunity with a variety of folks. But a key partner in thinking about this has been the Mayo Clinic. And we've been concerned that there hasn't really been a place where you could convene the conversation at a time where you could also leverage the emerging resources. And so, we've seen an opportunity to think together about how we could create a place and a set of capabilities, but also relationships that would

allow us to begin working at that calculus that we're talking about. How do we leverage data, but how do we use data in the most meaningful way?

So, Mayo Clinic I think you know well, and you also heard a little bit about it yesterday. I wanted also to place where our organization, Optum Labs, fits in this constellation of United Health Group. United Health Group is a big company; it's a Fortune 17 company, and it's involved in basically every aspect of health care. The United Health Care is the benefits organization, which ensures across a whole variety of different product lines.

A separate set of companies within United Health Group is Optum. Many of them you may have known in the past by names like Ingenix and Humedica. But they – we've come together now as a single company called Optum, which focuses on health services, focuses on consulting, focuses on technology, also focuses, to some degree, on care delivery. There are now several thousand physicians who work within Optum, within both medical groups and also in supportive roles to deliver care.

So, within that, we've stood up this new organization called Optum Labs, as a separate business unit, to think about, "How can we represent a variety of different perspectives, both from within Optum, but within the other folks who we serve," and thinking about, "How can we, again, solve this calculus about the interface of how we support care."

And it's not just about Optum in Mayo. And it's our recognition that big problems are going to take big problem formulations, and they're going to have to reflect multiple perspectives. So, we think it's really critical, if we want to be able to address the big problems, that we create a big enough table so that people around that table can help us be aware and sensitive to all the different perspectives that are critical.

So, there are the perspectives of technologists. There are the perspectives of academia. There are the perspectives of clinicians. There are the perspectives of life sciences companies. And it's critical for us, as we evolve these new problem formulations and think about how we stand up both architecture and technologies, that we take into account all these different perspectives and realize that it's really tough to resolve some of the conflicts and ambiguities. But if we're really going to create a learning health care system, we're going to have to deal with it.

So, on one hand what draws us into this is the fact that technologies actually create the ability for us to ask questions in new ways. So, the technical engineering is really a critical step. But I think, as all of us know, who have tried to implement technologies in one way or another, the social engineering is the ultimate differentiator. And so, a lot of standing up partnerships is really thinking about what are the social needs, and what is the social engineering? How do you organizationally support these?

I think there are blueprints, and our blueprint – and this is not really meant to be a vision test – but it's meant to just recognize that the social engineering is complex, but it can be approached systematically. And as we think about relationships, there are a variety of different domains in which we have to be attentive and think about, "How do we actually form relationships so that they meet the needs of the partners, no necessarily impose needs on the partners?"

So, this is a beginning list of thinking about the things that you have to work through in creating these partnerships. And each time you bring in a new partner, you have to rework the

relationships with the others. The goal here is to develop a bigger coalition across the folks that we talked about.

So, there are examples here, and I won't really run through them all, but it also has to reflect and respect the fact that different folks will have different ambitions and bring different things to the table. So, even thinking about with participation and research, there may be partners who will primarily want just access to the data. We recognize that. We also think, in the long run, that's not going to be enough. We're interested in folks who will also help us think about collaborative projects. How do we test the ability to reconcile these ambiguities by how we actually confront a project?

And it's also very important, as we move further to the right, we're getting into the mode of sustainability and governance in thinking about, "How do we ensure, analogous to a study section, that the way that the resource is used is the best possible use of the resource?" But also, that we've taken the perspective of folks, like the pink sheet you get back with the comments about how to make your grant better the next time, "How do we also ensure quality improvement along the way so that the way we use this resource of growing data is used in the best possible way?"

Well, we have a lot of data. So, we have claims data that reflects over 100 million lives over the last 15 to 20 years. And an important comment of this is that this data doesn't just happen. It has to be curated. It has to be cleaned, and it has to be preserved, and it has to be presented. But it also can be enhanced, and so it's possible to take claims data, as we have, and enhance it with a variety of variables that reflect socioeconomic status, and race, and education, and geography.

It's also important to combine it, though, with other data sources. So, I mentioned Humedica before. If you're not aware of Humedica, Humedica is a company that works across EMR platforms to create a standard data model, be able to import data from EMRs, both from structured text and unstructured text, through natural language processing, and create hundreds of variables in a standard research model that can then be used for further research. And we'll talk a little bit about how those can be combined.

We also have other data partners who contribute. For instance, I should mention, too, the Humedica data allows us to get at those clinical variables that are so important to round out things that aren't available in claims. And part of what we're learning also is the complementarity between claims and between clinical. Particularly in places where people go from one health system to another, understanding the actual course through care requires both.

But as we think about this going forward, we also realize that we want to increasingly grow the database, not only in terms of numbers, but more importantly, in terms of the diversity of the data. So, we also have a publically announced partnership with AARP, for instance, which has a very large source of consumer data that allows us to further complement and extend our ability to understand the individuals we serve.

So, our ideal is to work with partners to also grow the data resource so that we have a very robust reflection. But, at the same time, part of the enabling of this is trust and being able to both be trusted by the patient, by the clinician, and by our partners. So, we work with the identified data. The data that we have is anonymized and de-identified, either through a variety of statistical means. So, we don't receive PHI within Optum Labs.

But we can also, through technologies like being able to salt and hash and link together, we can receive de-identified data from a data donor. But we all know that all of our data donors de-identify their data in the same means, using the same hashing approach. And then once we combine the data, we can actually link together the claims data with the anonymized clinical data, so that we have a very robust data picture of individuals.

It's also important for us, though, to demonstrate that we have adequately, statistically de-identified this so that there can't be re-identification. And we further reinforce that by, within the labs, putting an additional hash in to basically anonymize the data. So, the data that we make available for research can get to the granular level of understanding the patient, but it's anonymized so that there can't be identification. So, we can protect patient confidentiality. Importantly, we can protect clinician confidentiality as we go forward and try and identify better practices.

So, the last couple of comments I wanted to make were really thinking about learning – the learning health care system as being a continuum. So, I self-identify as a health services researcher, but I would also reflect that as a researcher, I have worked on the supply side of the knowledge generation chain. We've tended to think that if we built up enough knowledge, publish it in the right place, that it will trickle down to the end user on the demand side.

There's a huge opportunity for us to think about, "How do we better recognize the knowledge and the wisdom of the demand side, and how do we ensure that the needs of the demand side, but also the experience of the demand side, are translated into research priorities and hypothesis generation?"

I think Larry Norton yesterday mentioned how 97 percent of clinical oncology experience is lost because we haven't figured out how to use the data. How much longer are we going to tolerate that? So, I think that this is a scheme that helps us recognize that hypothesis generation, methodology are very important on the supply side, but equally important and probably, we believe, a facilitator of translation is to ensure that the problems we work on, the way that we formulate problems, reflects the needs of the demand side.

And even more important than that is the experience of the demand side may be a critical way for us to begin working through some of the really complex problems. So, we're also very interested. We think that big data will only be an appropriately used resource if we use it to address really big problems.

And I think we also need to realize that there are certain problems that have been resistant to the ways that we've approached them in the past. Key among those, I would argue, is multimorbidity. And I think that one of the opportunities with big data is for us to rethink our problem formulation around multimorbidity. We've tended to think about it about the collision of very common diseases.

Well, what if we began to consider that the individual with multimorbidity maybe has an increasingly rare disease? We've talked about the *N* of 1. What if we began to recognize that the more complex your situation is, particularly when it's compounded by socioeconomic variables, compounded by geography, you become extraordinarily unique? The multimorbid patient may be a tail-of-the-curve phenomenon as opposed to being something that we can address with statistical means.

But the complement to thinking about that patient of an *N* of 1 is to say, "Rather than pattern matching that patient who's an *N* of 1 to the statistical mean of *N*'s of many, can we actually dynamically create reference populations that are many *N*'s of 1 just like the patient right in front of me?" And if we had that subset to work with, what could we do about evaluating and surfacing practices that are differentiating, that are being defined on the front line? Who are the clinicians that have already intuited their way how to better manage multimorbidity, and are we blind to them because of the way we've been thinking about knowledge generation and hypothesis formulation? So, I think there are big opportunities for us to work better with our communities.

This is just a list of things that I won't really go through; I think I've touched on all of them. But it makes a point that there are technical requirements for partnerships that can be addressed systematically, but we also need to think about the business requirements. At the very top of both lists is going to be this issue about privacy protection and thinking about how we can deal with that. But the other part about that is that we can deal with that, and we don't need to be stopped by that.

The other issues that I think are really going to consume a lot of time are going to be thinking about governance and sustainability. That was a key theme yesterday and perhaps something we could talk about further.

So, we're excited about the possibilities. We also see a lot of work ahead, and we'll look forward to the discussion.

Thanks.

Amy Abernethy: Hi. I always learn when I get a chance to follow Paul. I'm Amy Abernethy, and this is my disclosure slide. I also chair ASCO's CancerLinQ Advisory Committee. So, since I come from the academic space, it's sometimes hard to figure out what our conflicts are.

I always think about the role of learning health care from the standpoint of the patient. Paul just reminded us that he was curious what the two gentlemen in the very first slide were talking about. What's going on at the clinical front line? And the clinical front line is the combination of providers and health systems ultimately taking care of people, and people like every one of us.

And so, I think about learning health care in this frame, where learning health care is a bridge between research and practice, where each is forming each other through data, so that the care of an individual patient is informed by all people who came before her with similar characteristics – Paul's N of 1 story – and her care is reinvested into the overall system of continuously aggregating big data in order to take care of people in the future.

So, that's the vision. And we've been talking about big data, and George Bo-Linn yesterday reminded us that we're perhaps right in the center of the hype. But ultimately, it's got the opportunity to do a lot of work for us, but we ultimately have to get under the hood.

Yesterday, I believe it was Robert Jesse who said that health care is still about stories. It's likely the small data is the thing that's really, truly make change. And so, what I want to do is walk through a series of three stories today at the clinical frontline, thinking about other kinds of

partnerships and what that means in the context of big data. Because as we talked about yesterday, there are some critical issues here: quality, data gaps, how we use it, keeping from getting too overwhelmed by all this information flowing to us and at us.

And one of the important spaces is the mobile health space. The ability to use tools and technology, not because tools and technology make our lives full of blinking lights, but because they actually make our world more functional and allow us to spend more time, ultimately, with patients. And so, I'm going to use three stories to try and talk a little bit about other partnerships that I think are important for the big data story.

First is work we were doing at Duke specifically. And so, this is the story around tools. So, we were really trying to figure out, "How do we make sure that the patient story is directly embedded in the process of cancer care?" Every patient, therefore, was asked and has continued to answer, at each clinical visit, a series of patient-reported data questions, patient-reported outcomes questions – basically the same thing as a clinical review of systems – and doing it in a standardized structured way at every visit so that information is coming in. We'd have a longitudinal story of a person's pain or constipation or fatigue, and that that could be used to inform care. And that the process had to be reorganized.

It also meant that we ultimately had to develop tools at the point of care to keep doctors and patients from being overwhelmed. Spent a lot of time talking to clinical providers about what it was that was needed, and I'm not going to really talk about the process reengineering right now, but actually point to something that at first I didn't understand. And then I thought about it for a second, and I said, "You know what? As a doctor, I'm a pattern recognition person. I learned to recognize EKGs, and I've got to learn how to present the information that we're bringing in through these big data constructs, like continuous data aggregation, in a way that reflects doctors' and clinicians' expectation of patterns."

So, how do we use data visualization, like what's up in the upper left-hand corner, to bring the data that's coming in and make it make sense for the clinicians at the front line? We need to use our data structures, our warehouses, our databases to solve that problem for us, but ultimately, what the clinician cares about, not is that we have a fancy database, but that we actually have something that's usable in the clinical front line.

Meanwhile, we spent some time with patients and said, "What would it mean for you to keep participating in a system where you answer questions every time you come in?"

And patients said, "You know what? I'll answer as many questions as you want, as long as you make it meaningful to me. First, make sure my doctor endorses the fact that he or she heard what I had to say, and that it was important." So, we need to make sure that the reports are available to clinicians at the front line and are meaningful. "And second, if I tell you have problems with constipation, teach me about better management of constipation, don't teach me about how to manage my pain, 'cause that's not my problem today. So, match the education, the things I need, to what is going on for me."

Ultimately, what happened as a part of that story is that not only did we better bake the process of data collection and structured data into the process of care, we built tools that clinicians and patients needed, and that what we saw was that data quality went up with each visit; it didn't degrade with each visit, because the data were more and more meaningful. And therefore, data missingness went down, and we were able to run better reports and also analyses.

Second story. So, now, moving beyond the health system to a region. In this particular case, it started off across the state of North Carolina, and now has recently been funded generously by HRQ to move across the country. The question was, "How do we create, using mobile health solutions, point of care quality monitoring so that in real time, palliative care doctors, who may be seeing patients in the clinic, the hospice, the nursing home, in the hospital in the ICU, had the ability to understand whether or not they were doing the right thing, and whether or not they needed to amend care?" And that this needed to reflect the patient experience and quality of life, and at the same time, it needed to be able to tell clinicians whether or not they were doing what they needed to do in a way that didn't get in their way.

We brought doctors, nurses, information architects, statisticians, technology developers together on the phone every two weeks to ultimately develop the system. What did we do, and what did we learn? Well, ultimately, we learned that first we had to figure out, "What were all the quality measures, and how do we make quality measures machine readable?" Ultimately, they have to be something that we can analyze and work with. We had to make sure that each of those groups of people knew how to talk to each other. We had to make sure that we ultimately developed solutions and tools that met those clinicians where they were, including all those different settings, and that ultimately could drive their clinical practice without getting in the way.

As a result of this, across the state and now across the nation, we're continuously aggregating structure data that's being used both for point of care quality monitoring, but is also continuously feeding palliative care registries that we can use to now link quality measures to outcomes, again because of teams and partnerships working together.

And finally, the NIH collaborator program. So, I run the patient-reported outcomes core in partnership with Kevin Weinfurt for the NIH collaborator, which is a trans NIH initiative to really try and bring together the data across health systems to conduct large, simple trials, and seven trials are about to get underway.

One of the things that one of the trials being done in Kaiser Permanente taught us was the importance of recognizing that not all data is in the EHR in a way that can ultimately be used, and we had to ultimately supplement that process if we were going to be able to have the data that were needed in order to inform this research and care.

And so, what this particular program, the Kaiser Permanente program, did was the data were coming in, as required by Kaiser, but needed to be essentially reviewed and worked through in an outside system and a solution handed back to providers, and that researchers who needed the data actually had to be involved in that process because they needed the data to be in place and not missing.

And what we saw happen as part of this process was that the development of outside EHR technology solutions, coupled with the EHR, ultimately led us to the point that then the patient-reported outcome data was present and was able to be used for research with the context of large, simple trials, and that this information is now being shared about how to do it across all the other collaborator projects, and subsequently now into the PCORI NCRN program.

So, ultimately, what did we learn? We learned that if we can make data learn for – work for us, then at the same time that the data is working for us today, it's more – it's higher quality, more structured, and less likely to be missing tomorrow. And that by doing this kind of very careful,

under-the-hood work, we ultimately are able to get the variables that include the outcome variables across time that we need for our big data story in the future.

Underneath the hood, it ultimately is a lot of work and requires all of those kinds of partnerships of people working together. And one of the things I submit to you is that what goes on in the clinical front line matters a lot to what kind of data you have in the future. So, with that, ultimately, what I'd like to submit is that we need to make sure that we've got policy that does focus on having demonstration use cases of how to do this, and having a workforce, ultimately, that knows how to do it as well.

So, with that, thank you.

Lynn Etheredge: Thank you to all three panelists, all I can say is my overview which said everything in healthcare is potentially changing and is already being revolutionized by finding new ways to use data, I think has just been illustrated many times over. An astonishing amount of things are getting going and I'd like to think this is just the beginning, but we, great chance to learn from the pioneers here. Let me ask a couple of questions and then we'll see if the panels have some questions they would like to discuss and then I'll go to the audience. You know particularly as I was listening to all three of you who are all both Sam and Paul are involved in enterprises that are almost the size of entire countries, 30 million plus people.
If you are responsible for their health and you're involved in everything from research to deciding what best practices and actually delivering care in changing lives of patients.

And Amy's involved in a whole range of things including the NIH National Research Collaboratory. So this being Washington, let me start with some sort of national policy level discussions because I hope we can learn from all of your experiences about what still needs to be done at a national level. So let's start with data since that's kind of the key here. If you were being asked about national data strategy and some of us saying well what are the gaps, where do we most need to invest in ability to get even more benefits from data? Is it new technologies, surgery, which is outside the FDA process, patient of the month, that Paul mentioned, pediatrics, what do you think of is the, what advice would you give to, if you were asked by for example, by the new NIH head of data science what the national investments would be that would be most, have the largest pay off? Who would like to that, you would like to take that on?

Dr. Sam Nussbaum: We all will Lynn.

Lynn Etheredge: Okay, good, Sam, lead off.

Dr. Sam Nussbaum: Sure, be happy to. You've asked a number of compelling questions and let me start by thinking that if we're gonna take on new technology, we know we have an affordability problem in this country and we have a quality problem. Every group that looks at the way that we have healthcare expenditures, you know most recently the Institute of Medicine, we find 30 percent of what we do is not evidence-based, it's not effective, it's wasteful. And we need to remove this 30 percent so we can continuously have the headroom for innovation, the innovation as we approach breathtaking biologies who understand the human genome as we have whole genome sequencing and decide how to apply that. So I think the very first thing we need to do is not look back on past technologies because we have very ingrained behaviors and clinical practices, but I think we have to look at the new. And the new is how we use molecular diagnostic testing, how we look at specialty drugs and their application, particularly as we know that the biology of cancer is being rediscovered in many ways. So the first part of it is let's look at areas of proton beam therapy as a very specific example, what is its optimal clinical use for patients. If we can understand those we can begin to get our arms around these extraordinary new technologies that are very expensive and then we can perhaps take some, and should take some look back.

Now in terms of just a word about the data environment, I think we learned a lot from the Mini-Sentinel system and we, some of us who were very involved at its inception recognize that we could use a distributed data environment to get meaningful information very quickly at relatively low cost. And I think we have to model that approach to see whether it's health plans, whether it's delivery systems and physicians now that they have more and more electronic capability. I think that's a way of starting; now it's not again the big bold national strategy of having a national database but it enables us to begin to look at issues. And then to begin to understand what do we need in this new database and how can we construct it in a way that is efficient because I pointed out that we have so many activities going on at the state level and employer level and Medicaid level, and the more that these can be harmonized we can see that investment proceed wisely.

Lynn Etheredge: Sam why don't you just pick up on your two points and we'll get back to some more general discussion but I want to follow-up particularly on new technologies because, and cancer was a great example because both Amy and Paul are oncologists and I have the privilege to work with them in developing the ideas that led to the rapid learning cancer system in ASCO. Amy let me just start with you because I know you've actually looked at the existing system we have for evaluating new cancer

technologies and that's, which is less than perfect, so you might give us a description of what that is, a critique of it. And also the challenges that are going to come up as we have this whole new generation of targeted therapeutics that are going to be aimed not just at old diagnosis like lung cancer but at a pathway that might be common to many diseases and we can't run randomized clinical trials on every pathway for every cancer. So help us sort this out if you would, Amy.

Dr. Amy Abernethy: Oh it's interesting, it was actually through a project from CMS that I first got interested in this question of what was going on in cancer and how are we gonna sort through it, and that's how I ended up in the learning healthcare space. There is a legislative action that allows for the payment for oncology drugs in the off-label setting provided that they have been appropriately approved by the FDA for one indication and that there is some evidence and recommendation of use within a series of authoritative resources called the compendia. What this leads to is approximately 65 percent or so of oncology drugs especially the targeted therapeutics being used in what we would the off-label space which ultimately means that if I have a patient who has for example a diagnostic finding suggestive of the appropriate use of this drug even though that was wasn't the reason why it was FDA indicated, I can prescribe it for my patient and have it be reimbursed by CMS and many of the third-party payers.

What's happened therefore is essentially a huge constellation of INNOV1 experiments, I think this is part of what Larry was describing yesterday was we described about 97 percent of cancer patients not having their care reflected in any systematic way in our data sets. And what this ultimately means is that patients have biologic as well as tumor and personal findings that ultimately lead their clinician to make a decision about a drug in the context of their disease and then some outcome. And so we have essentially many, many INNOV1 experiments going on all the time and need some kind of logical way of storing and summarizing that. That's really been the background and the impetus for ASCO's cancer link system as well as the conversations around learning healthcare and cancer is really to try and sort through that because it's not just this particular decision today for the cancer patient, it's actually making this particular decision about this particular drug reflecting what the patient's prior drugs may have been and their prior personal history and experience and also what drugs they may be getting in the future.

You know a couple of observations, the one that always comes to mind here is that it's a longitudinal story and there is the critical need to have outcomes in it. So as we ultimately develop data systems and ways of ultimately digesting or ingesting a whole bunch of information, that information is not gonna be necessarily meaningful and help us work

through this series of all these INNOV1 experiments if we don't have enough information about the particular patient, their longitudinal story, and the outcomes that go along with the story. So that's the first thing that I see as a part of this. The second thing is what Paul was talking about before which is we need to understand both from the analytic side as well as from the what is evidence side about how we're gonna make sense of this and then decide how we're gonna reapply it into practice. And the third is that ultimately as clinicians we're busy and overwhelmed already and so the solutions that come from this as we try and work through all this information and data ultimately has to have meaning for me today and we need to have tools that happen within the context of these systems of plaintive care.

Lynn Etheredge: Thank you, Paul, more on new technologies and how to evaluate them?

Dr. Paul Wallace: I think a lot of the challenge is that we're moving into an era where we need to be able to hyper personalize care for a whole lot of reasons and it has to do with both our understanding of disease. So you know and I trained as an oncologist, we want to gather things by organ, so like how 2005 is that? And so I think we have to realize that we're defining conditions in a much more precise way. But I think it's the analog and the multi-morbidity problem that we have to sort of go through the looking glass and leave behind the means and, you know the statistical mean of distributions and think about how do we assemble appropriate reference populations whether it's patients with a genomically defined cancer or whether it's people who are, have a situation that's defined perhaps by their socioeconomic status in the collision of a variety of diseases.

So I think that that metaphor will carry forward, but I think it also gets to thinking about how we validate the utility of new technologies or new drugs realizing that the goal here, the opportunity around personalized therapies was that we begin to approach number needed to treat of one or two as opposed to NNTs of like ten. And it also means though that the way we think through cost effectiveness will change. When we have therapies that have very small number needed to treat we actually are quite willing to spend remarkable amounts of resource if we have high confidence that they'll work. But part of the way of working through that is also to recognize the other confounder which is heterogeneity of treatment effects.

And so it also helps us look within a population that we're exposing to a technology or a drug, who are the subpopulations that do respond well and who are the ones that don't, so that when we actually get things in the marketplace we can focus them on where they work really well. Gleevec is sort of you know the best example for this, but also there's sort

of a moral hazard because there aren't gonna be very many Gleevecs but there will be analogs to Gleevec that'll be a little more complex and how we have to validate, how we have to find, and how we have to use 'em. But I think the same thing applies to how we think about technologies, if they're really aren't gonna be that many more blockbusters and we have to really, the blockbuster is predicated on being able to leverage the statistical mean of end of many. The issue here is how do we actually go through the looking glass again and think about the end of one and how do we actually ensure that we've matched the intervention for the needs of that individual.

Lynn Etheredge: Let me ask a related question which is, it gets to how do we actually decide what questions we're going to pursue given that there are all these data and all these needs. In particular I'm concerned about the Medicare and Medicaid populations, partly this is my old OMB background but we're spending close to a $ trillion a year now or soon will be in those two groups, and as you analyze those populations the senior citizens unfortunately are in that group of complex co-morbidities often, a group that doesn't wind up in clinical trials usually, and similarly the majority of the Medicaid dollars are going to seriously disabled, chronically ill populations that often with mental and behavioral problems and they tend to be outside the clinical trial system. So what are the strategies we use to try to develop a national research program that would give us the most leverage on Medicare and Medicaid, any of you guys want to take that on, Sam, Paul, Paul's got the answers.

Dr. Paul Wallace: I'll start, we'll do this in a Donabedian way and I'll take the structure part but to me one of the, and it actually goes back to one of your earlier questions too, where I think you know if you think about where we've been creating proof of concept, it tends to be more in commercial populations than Medicare or Medicaid populations. So we have this challenge about how do we actually extrapolate learnings, but the other part is to realize that the vast majority of practices are actually multi-payer environments that are dealing with really all payers but we're, we've made ourselves blind to that because we've siloed how we keep track of the data.

So to me one of the larger opportunities is actually I think Sam touched on this before too, is to think about how do we create all payer data resources that we can actually go to. And then what we can begin to do is to do the crosswalk between what we observe perhaps in a clinical trial, but how do we then do the observational study that complements and extend that to understand how does that actually apply to a population that might be defined a little different than the group that we did the original trial on. So I think that part of a way, if you guys just think back a

couple steps to structurally if we want to relate across populations, if we want to fully leverage practices we've gotta have resources that reflect the whole population.

Dr. Sam Nussbaum: I know that Joe Selby will be chairing the next panel or later panel and I think we have to look at a PCORI as one of the most innovative solutions. I think if we look at the Affordable Care Act there were too many, many jewels in it, but two that particularly were the Center for Medicare and Medicaid innovation and PCORI. So PCORI's has gone out and it's looked at how, what are those research areas that we should address? It's done it in a way that certainly balances patient interests. All of us have had opportunities to, going forward to, will have opportunities to participate in learning collaboratives, but I think importantly it is a structure and funded through health plans, funded through Medicare/ Medicaid to absolutely set that right agenda to answer those questions.

You know we have issues when we talk about how much we can focus on the cost effectiveness, but I think that is one arm and then CMMI represents a different arm and that's an implementation arm of ideas and strategies that may come out of the research of PCORI. So I think if we look at the innovations grants and PCORI, we have that capability, the question is we have thousands of points of light out there, think of every state Medicaid program that is, Lynn as you say, is it's a huge financial burden for those states. Those states are making decisions to, do you invest in the sort of social determinants of health, right, in education and other infrastructure or do you spend the dollars in healthcare?

And I think they have a real strong stand in terms of the questions that should be asked. So we need to find a way of probably bringing those individuals together besides their current organizations to also allow us to ask the questions. And then finally you have as both Amy and Paul have talked about, we have the ability now when those questions are posed to us to much more quickly, in a real world research environment, in a real world outcomes environment, to begin to answer them with these large populations that are cared for by both the providers as well as the financers of care.

Lynn Etheredge: I think that that's right, I think the, I would view as a part of the job description for CMS administrator ought to be setting research agendas for the research agencies and public health service. Those are two parts of HHS that seldom have talked in the past although I know more of that's going on now. So let me turn to Amy to answer this to see what she has to say on that question, but this panel is so good at answering questions, I'm gonna turn to the audience questions right after we hear from Amy.

So if you got questions you should start getting them prepared and we'll get to you in a second. Amy –

Dr. Amy Abernethy: So what I'm gonna say is sort of heresy to my tribe of researchers 'cause that's where I come from and that's that as you said CMS and our colleagues from PCORI et cetera, we've got the opportunity to set the research agenda, we should be doing that from the national level, looking at what is the low hanging fruit that we need to deal with? In this room was the IOMCAR priorities meeting, we said let's work together to set the CER priorities and we actually need to do that work together. One of the things that PCORI has worked on and I think is part of the agenda setting that we need to put across all of our agencies is making sure that the community of all kinds of stakeholders who have the downstream impact of the research that we do is a part of that agenda setting. And so for example patients and families are a part of saying, "This is what matters to me."

Two other observations, one is that there is an entire work now going on especially outside the United States, a value of information analyses and understanding what's the most important information that's gonna be most impactful and we need to learn how to bring that process into our agenda setting so that we're actually doing things in a thoughtful way. One last comment is that our organizations like our clinical trials networks need to be partnered with other parts of our health system in the big data space like registries and electronic health records so that when we identify areas that are high enough value to go into our clinical trials organizations that we are ultimately able to then monitor the outcome of those trials as it starts to bleed out into clinical practice by monitoring our registries and other activities.

Lynn Etheredge: Great, well let's start moving to our audience, as you, clearly this is the panel that can handle any, virtually any question you can come up with so let's start over here, if you'd identify yourself and ask your question.

Dr. Caroline Poplin: My name is Dr. Caroline Poplin, I'm a general internist, I'm also an attorney and I have worked on some Medicare/Medicaid fraud cases where the fraud involved was off-label marketing and we noticed that some manufacturers are using the registries of, and all this data to pick the cases where their drug has performed particularly well and have left out cases where their drug hasn't worked so with all this information they're able to manipulate the information in order to make their product look maybe better than it would have looked in a randomized control trial. And there aren't really, I don't hear from you that there are sort of rules for this, I mean it's a wonderful opportunity to develop learning for, that we

can all use, but on the other hand are you concerned about the fact that people who have a financial interest in the result may manipulate the data to accomplish their result.

Lynn Etheredge: Okay, who'd like to take that one on?

Dr. Paul Wallace: Yeah, well I mean sure, and I think that big data is not an excuse for bad science and I think –

Dr. Caroline Poplin: But it's an opportunity.

Dr. Paul Wallace: You know I think the point, of course it is, but there, you know there's been opportunity in the past and so I think it also means that big data also gives us an opportunity to heighten our vigilance of how we go forward. I think that's a lot of the work of OMOP is to say that you know I think if we think sort of metaphorically about how we've observational research in the past, when data was scarce and rare observational research was sort of like parachuting in behind enemy lines and then seeing if you could escape before either the IRB or HIPPA got you.

And I mean that's not the context and the point here is that one of the things that's possible as we go forward is to be very thoughtful about how we collect data on all patients so that our downstream observations can have increased validity. So it's not about cherry picking how we collect data or who the patients are as thinking about how do we view every patient as an INNOV1 trial where their information is every bit as valuable as somebody else and then leverage that in a way that we can mitigate the risk that you identified. So, but I think that there's a lot that we need to learn about those methodology but also the regulatory environment so that we can ensure that we keep that promise to the public.

Lynn Etheredge: Well, Amy –

Dr. Amy Abernethy: Well you know I see what you're describing really is gonna be what I call the fraudulent end game which is at the marketing side there is presentation of findings that really are distorted. But in fact there is the important aspect of making sure that we do the best possible work all the way through the big data analysis food chain and that includes making sure that it's very clear how we maintain data prominence, making sure that we are very clear and transparent about the algorithms that we use

and allow people to ultimately check our work in multiple different directions. And one of the things that we've seen in our research is the critical piece of getting the results back to the clinical front lines that you're getting feedback from providers, from patients, and from payers so that ultimately that feedback loop helps to make sure that the analyses that you're doing and the way that you're working forward actually makes more sense. One of the biggest risks is that we ultimately sort of develop the GPS of big data and that ultimately we think we're going to Baltimore and we end up in LA because we weren't paying attention to how we got there.

Dr. Sam Nussbaum: A practical standpoint, most of the health plans have very extensive groups of structures that are put in place with oncology experts for example to look at the clinical trials. We certainly endorse off-label use when there's science behind it so there is at least that sort of oversight that takes place to, again it starts with data but to limit the application of treatments that may not have promise for any individual.

Lynn Etheredge: Okay, next question over here.

Linda Schwimmer: Hi, thank you, Linda Schwimmer from the New Jersey Healthcare Quality Institute. My question I would describe as really a walk the walk question, I think it's wonderful that we have all this data and that we have Watson and we have the Optum Labs but how is that going to translate into the delivery system and the payment and incentive systems? It's doing so now in a very limited way I would say in terms of some of the CMMI, the Innovation Center projects and some patients in our medical home projects, but while you have that excitement and innovation happening, for the vast majority of people that are utilizing the healthcare system and for the vast majority of hospital systems and providers, particularly those that serve the dual eligibles and the Medicaid population that you were referring to, we don't see that change happening.

There's a bit of a disconnect between all of this data that we're collecting, that shows us what interventions work and what these populations really need and then the contracting element of things. I'll just give you one small example, we're seeing a particular plan that's paying the same reimbursement rate for primary care and Medicaid whether it's on the scale of complexity, the lowest complexity or the highest complexity which obviously incentivizes providers not to see those high complex patients. So what happens, they go to the emergency room. Same thing on social needs, there's not that connection to, we see in the data what they need and then the delivery system, so I'd love to get your response –

Lynn Etheredge: Fundamental question and this is where you guys live every day is how do we take the best practices or better practices and get them implemented? Sam –

Dr. Sam Nussbaum: This is exactly where we live and this is exactly what is so fundamental to making the change that we all want in our healthcare system. I gave some examples and although I didn't go into them in great detail, today hospitals in our networks are paid based on about 47 performance measures and these are real outcomes of care, these are based on quality and safety measures, I can share those with you at a, if you'd like. But what we have done is said more and more of the reimbursement is truly based on outcomes and for a hospital three, four, five percent matters. For physicians we've been moving down this path for some years and what it's about is not only paying more on a risk adjusted basis, that was one of your comments for complexly ill individuals, but paying differently.

So in our medical home, in our patient center medical home programs we are both paying management fees, so care management fees for the primary care doctors, but in addition have moved to what we called shared savings models, and these models look at the cost of care of a population, what medical trends are, and if you can improve that trend by giving better care. So preventing unnecessary re-hospitalizations, emergency room visits, along with again about 40 quality measures, performance measures that are gating events but if you hit the quality gate and you can show more effective use of resources you're gonna share about 40 percent of those dollars.

So we're not trying to create insurance companies for clusters of primary care doctors, but we're trying to incent true clinical results performance using information in meaningful ways and on top of that it's to give information. For example those individuals at greatest risk for deterioration in health understanding through claims and chart review in some instances or EMRs where there are significant gaps in care, in closing those gaps. So we're really not only our company, but I know UnitedHealth Group and Optum and almost every health plan is truly moving in the direction that you're advocating.

Lynn Etheredge: Well I know this is a big issue for Optum because you guys are coming up with a better answer but then you want the other half of the company to implement them so what do you, how are you approaching this?

Dr. Paul Wallace: I guess it's sort of what I alluded to before about how we organize the demand side in a sense on a couple levels. One is to, one of the key issues to me about translation is to ensure that what you've created is knowledge is relevant to the folks who would use it and I think there is a huge waste that goes on when you look at actually the number of things that get funded, get published, and then lie fallow that that's a big concern. I think part of it is because a lot of the stuff that's investigated actually isn't all that relevant to people on the front lines. So I think it's very important that we close the loop so that the questions are being answered are being addressed actually are relevant.

The other part about that though is that I think that the way that we formulate the problem needs to take into account the major stakeholders so that's why the, that's really why our intent is to ensure that we up front recognize where the tensions are and the ambiguities as we create solutions or ways to move forward so that we're not blindsided when we attempt to translate because we haven't anticipated how it plays out. I recognize that it's still sort of at the 10,000 to 20,000 foot level but I think we also have to realize that we are in this incredible transition right now with thinking about how do we move from what historically has been a sixth of the economy that's based on volume and we're trying to change it to how we basically move that economy to being based on value and we're not there yet and it's gonna be kind of messy and awkward as you go along the way.

But I think that the good news is that the lubricant for that discussion I think is going to be data and transparency. So I think continuing to ask that question and push for answers and then come up with the use cases that demonstrate that it actually is moving into more of a value space than a volume space is part of the catalyst for them.

Dr. Amy Abernethy: And I'm gonna add one additional piece which is although not related to the reimbursement driver per se in closing the loop, the professional societies are gonna become progressively more important here, helping to define quality measures, reorder quality measures, do workforce training across different specialties including both primary as well as subspecialty medicine and non-medical disciplines. So I think that that's also an important part of closing the loop and we're seeing that both at ASCO and American Academy of Hospice and Palliative Medicine right now.

Lynn Etheredge: I would just underscore two points here, the one picks up on what Amy just said which is I've been very excited about what ASCO has done not only because of cancer in that it's a model as a learning system but because it's a example of what I think the power of the specialty societies

could be is the health policy guide I think for about the last 15 or 20 years, ever since we started talking about managed care, physicians have been in a funk.

They've decided they're being treated like employees although they're at the center and what they do is at the center of medical care and in frankly none of the reform strategies that people talk about work unless physicians are part of them. And they haven't been, felt they've had a leadership role or a buy-in in many of the strategies that we've come up with in Washington. So I'm excited about specialty societies as reflected by ASCO is that they're an example of where we can take our, these physicians who are well-trained is at the leading edge of being using science themselves and encourage them to take a leadership role in shaping the evidence base, the questions, and the applications.

So I would hope that we would be, and we are beginning to see other specialty societies starting to get into building registries in research networks, pediatrics, there's work in cardiology, and so forth. So I just want to underscore we could see some new dynamics coming in with big data with a new role of specialties and as Amy had said earlier, patient, the informed patients can be very important with mobile health and other environment. We can put predictive models and other information much more reliably in front of patients so they can be a much more active force in trying to see that they get the best care. So let's move on over to this side.

Josh Rising: Great, thank you, my name's Josh Rising, I'm with the Pew Charitable Trusts. One area of our healthcare system where we don't have much big data at all is on the performance of medical devices once they get FDA approval. The FDA is now requiring manufacturers to have a unique device identifier that will be on the label of each device which could go a long way to help improving our ability to get post-market data on these devices. We've been working hard to make sure that the UDI is captured in electronic health records and on claims forms for implanted devices at a minimum. I'm curious to hear your thoughts as to how your different organizations might be able to use the unique device identifier for patient care and patient improvement down the road and if you've begun taking any of the steps to get ready for the unique device identifier. I think on the highest risk devices it'll start appearing within the next nine months.

Lynn Etheredge: Very good question, very timely, who would like to take that one?

Dr. Paul Wallace: I guess one way I would think about it would be, I think it's important for us not to create unique point solutions but to take sort of a problem

statement like that and think about how does it actually catalyze a larger solution. So to me where I see, where that takes me is I think okay, if I want to keep track of those why would I only keep track of those, why wouldn't I link it in with other patient data which very quickly takes me to a registry. So it also asks me if when we create our registries of people that are having hip replacements do we have an appropriate column to capture that data?

So I think we have to be really, you know as we think about big data we also want to be sure we create big enough solutions so that we don't just create a whole bunch of other niche satellites. So to me it's sort of how do we incorporate that need into a larger strategy like a database strategy and then how do we incorporate registry strategies into how we think about post market surveillance which actually frankly very quickly is a slippery slope, you're thinking about how do we actually think about new models for both entry to market but then exit from market for things that are proven not to work, so that's kind of where I go with that.

Dr. Amy Abernethy: One of the things that we're seeing as we work on registry development, including within the context of the device base is the more that we just add another variable to collect that needs to be collected by the clinical provider, the more burden there is on the system and also the more likely it's gonna be missing especially when you really needed it collected. So one of the things that we've been trying to think through at each particular need solution that we're running into is what are the passive pieces of data that we can collect in the eco system around the particular patient or around the clinic to make sure that we are essentially populating this story in a longitudinal fashion in this passive of a way as possible. And that process really requires attention to the details of what correlates closely with the outcomes that you want and what information is gonna be of the least burden to patients and providers to get it. And I think that we have the expectation, the burden on ourselves to try and figure that out as we develop these registries.

Dr. Sam Nussbaum: On a more positive I do think that you know what you've described and what you've advocated for does fill a need. Look at every, some of you may have seen yesterday the large settlement over an example of a hip implant and we need to know that information sooner than before tens of thousands of people are exposed to those types of safety issues and those harms. So again is it as comprehensive as registries, should we be looking the same way we're looking at Mini-Sentinel or sentinel, should we be looking at devices? Absolutely there needs to be a larger framework but along the way there can be some approaches that will get us to a better place than we are today.

Lynn Etheredge: Let me follow-up on that general question by asking you, I'll mention it, electronic health records policy, let me explain that while you're trying to figure out what I'm gonna ask. When we get to constructing new registries, new data, being able to put together data we've made huge investments and are making investments of tens of billions of dollars, electronic health records of virtually every American that use, originally is designed to try to give us a basis for doing that. On the other hand we have a very limited set of requirements for what goes in those EHRs now and if you start looking at what people would like to add for cancer, like the whole genome sequence or cardiology, I think if they've got down to about 100 additional variables they would like to do for a cardiology registry and so forth.

And then we'll have the new technology registries, the sort of level of requirements that could be added in with some justification become almost overwhelming particularly if they'd be add to the expense of everyone trying to buy federally certified EHRs, so could you reflect back on where we should be going with national EHR policy and how do we sort out using all those investments to do a better job of building the data systems without overwhelming everyone with spending their time filling out data forms? Amy will take that on, of course Amy will take that on.

Dr. Amy Abernethy: Oh yes, yes, yes. So you know I always think of the EHR essentially as an electronic file drawer, it's the front end part of the story and really helps to organize and communicate within the context of the clinic and information comes in. And then ultimately has to be able to be stored in some kind of accessible way and we need to create the expectations around ourselves that we have information that's accessible and that we can do something with. Meaningful use sort of takes us at least to MU1 and into MU2, takes us a little bit of a step along the way. So first of all we actually need to recognize that the EHR is not the entire part of the story, that we need to be able to for example we were talking about devices, bring in information from many other information feeds in the API recommendation within meaningfully use three I think is gonna be critical to be able to start to think about how do we exchange information to our greater body of data not just the front end of the EHR. The other thing is that ultimately the way that the information can be structured and used on the backend is gonna be very important to us because for example one of the things we've been working on is in vermatics enabled registries, being able to essentially subsection off data marks in the backend of the warehouse that's generated from the electronic health record to do what we need to do in order to solve for example specific registry questions and problems. And I think that part of our task with electronic health records is not to think about electronic health records as the all-in-one

solution but really the front end to solve one set of tasks and a looking glass or entryway into global data solution.

Dr. Paul Wallace: I'd build on that a little bit too to say that there are some, it's not like it's a total desert where nobody's figured out how to use these things. I think there is some great examples of where registries have become really foundational in how practices are run and continuously improved. So one of the better examples I know about is the Kaiser Permanente Joint Registry where it works because the data is generated as a byproduct of the appropriate care being delivered by clinicians everyday and they're more than happy to do it because they know it allows them to deliver better patient care tomorrow. And so it's, we don't want to add work on that doesn't add value but we don't want to be shy about adding on opportunities that add huge value and the people that will help us understand that are gonna be the end user. So I would think that there's a design element here for us to understand and surface for these case studies where registries are becoming foundational, what are the operating characteristics that have allowed them to succeed.

Dr. Sam Nussbaum: Only that the largest impact in healthcare is still within specialty care when we look at some of the newer technology and we need to figure out how to customize the information that'll be in the electronic medical records of orthopedic surgeons, certainly oncology is an area that, so that capabilities and functionality need to be far more sophisticated and advanced in those areas, in those domains to get the knowledge that we need.

Lynn Etheredge: That's a good point particularly linking EHR development to specialties in new technologies, yeah. So is that Mark, yeah, hi Mark.

Mark Berger: Mark Berger, Pfizer Real World Data Analytics and for full transparency I should also say I have worked at Optum and I have also worked in academia. I'd like to address the issue of data infrastructure, data sharing, transparency, and replicability particularly as it comes to a earlier question about good science versus bad science. Having access to data is critically important so that people can replicate analyses, particularly with observational data where it's not quite as cut and dried as it in with an RCT into it, to do an analysis and you'd like to be able to replicate analyses. And I think patients are not gonna be the obstruction, if you did, there's a recent survey that was done, it showed that patients were more than happy to share their electronic medical record data if it was gonna be used for legitimate research purposes.

There are, and you've already talked about how there's quite the ability to de-identify the data and you'd hash things create de-identified data sets. So what then is the obstruction to actually sharing the data? Well the answer is that follow the money, everybody has an interest in how they control their data. Everybody sitting on the table here, all except for you Lynn, controls a data set and is not making it freely available. And if we did make it freely available sort of like what Optum labs was doing, but actually made it freely available then everybody could go up and do the research against that data and you could have replicability. You could have very quick crowd-sourcing to find out the answers and you could triangulate on that. But we are in a free market economy and not everybody wants to share their data 'cause it has value so how do we get to it, we got to that place with Mini-Sentinel because safety was a special issue.

How are we gonna get to a place where we're gonna get to an open source world where all this data, if it's being used for legitimate scientific purposes and you can protect patient confidentiality and also provider confidentiality? Assuming we can do that, how we gonna get to the place that everybody who has legitimate reason to get access to the data can get access to the data and it could be meshed together and put together into one large data set so we can get what you were talking about Lynn, which is, we could answer questions a whole lot faster because the feedback is hundredfold or a thousand fold. Why aren't we doing that and I think we know what the answer is to that but the question is how do we overcome that to get to a place where we're actually gonna drive forward healthcare improvement on a more rapid basis and bad science is exposed almost as rapidly as it's done. And I who have worked on so many methodology committees advocating for good methods, we will actually see those good methods being adopted broadly not just by people who work in a regulated industry but those who work in academia who don't always follow those rules or in payers who don't have to expose how they do their research at all.

Lynn Etheredge: Well there's lots, a lot of things in your question, is there someone you'd like to see, is there someone you'd like to see take the first swing at it?

Dr. Sam Nussbaum: I'd be happy to take, not a swing at you Mark, but a swing at I think some of the comments that you believe in. First let's just look at Mini-Sentinel and you see some organizations up here that were very involved in its inception and continue to contribute. We look at OMOP, PCORI now through a clinical data research networks, I think you're seeing that our organizations while information maybe a competitive advantage in some aspects that we are contributing to the broader science and policy and I

think that this is a journey that we've all been on as you know from, we do not sell our data but we are involved in over a hundred collaborations and that's what we believe in and that's the journey we're on.

Lynn Etheredge: Our chairman has just advised me, we'll take your last comment here Paul, but the chairman has just advised me we have to stay on schedule also, sorry we won't get to more questions or even more comments, but Paul why don't you handle that one and then we'll move on to the next panel.

Dr. Paul Wallace: All right, to me the two most difficult concepts we haven't yet mastered are on one hand, sustainability because first of all this data doesn't just happen, there are significant issues around curation and maintenance and security protection so sustainability is a huge piece. But there also is the other piece about governance and ensuring that there is appropriate use and where those kind of collide for instance, our de-identified data sets are only appropriately de-identified; they can't be combined with other data sets. So there are security issues about how these things are also made available, but we're in violent agreement Mark, that the object here is to make things available at fair price that reflect the cost of production but that aren't being used primarily to hoard data.

Lynn Etheredge: Amy, okay, for, give your last words.

Dr. Amy Abernethy: I was just gonna say Mark, I think you're probably familiar with the fact that Pfizer and others are participating in Project Data Sphere and this really brings together data from across pharma, academia, et cetera, and honestly part of it is we've got a practice how to do it as well. So in addition to figuring out the sustainability it's actually figuring out the legal issues and the collaboration issues and the trust issues and honestly it's not just the trust from the context of patient privacy, it's the trust of how do we trust each other that if I share with you that that's gonna be good for the common good. And there's been a lot of meaningful progress but anything that all of us can do in this room to keep that progress moving forward is critical.

Mark Berger: I hope that trust can be built more fast and that we can all get together and do this right.

Lynn Etheredge: Okay, much more could be said but it's time for the next panel so thank you all for your great questions and thank you to the panel.

SESSION 7: BIG DATA'S INFLUENCE ON COST AND QUALITY

Cost and quality issues are a long-standing and pressing concern for public payers, health systems, and public health. In this session we examine how incorporating new big data, including predictive modeling, facilitates our understanding and the ability to address the issues more efficiently.

Moderator: **Robert Crane,** Board of Trustees Member, ECRI Institute; Former Senior Vice President, Kaiser Foundation Health Plan, Inc. and Kaiser Foundation Hospitals; Founding Director, Kaiser Permanente Institute for Health Policy

Shari M. Ling, M.D., Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services

Stephan D. Fihn, M.D., M.P.H., Director, Office of Analytics and Business Intelligence at VA Puget Sound Health Care System

John Supra, M.S., Deputy Director, Information Management, Chief Information Officer, South Carolina Department of Health and Human Services

Nirav R. Shah, M.D., New York State Commissioner of Health

Robert Crane: Good morning. I'm Bob Crane. While I've spent most of my career at Kaiser Permanente, I've had the opportunity over it to work at both the federal and the state level, and so I'm particularly glad to chair this panel, because I think the alignment – the previous panel used the word harmonization, I think it was used – of the major actors that both shape the environment and watch its impact are represented at the table. We have a delivery system. We have two state officials doing innovative stuff, and then a representative from CMS.

Themes, through the last day-and-a-half, have really focused on big data and the need to transform it into information, knowledge, and hopefully wisdom. And many of the

speakers have also talked about the importance of starting with the end in mind, “What is it we’re trying to do?” And the subject of this panel really focuses in on one of those important – and so system improvement to improve both cost and quality.

Our first speaker is from CMS, and it’s not Patrick Conway, but his deputy, who, given some directives from the Secretary – the department is a little busy these days – had something else at the last minute that he was required to do. But I’m very pleased that Shari Ling, who is the deputy CMO at CMS, will start us out with a federal perspective.

Shari Ling: Good morning all and I thank you for including us in this timely and critical conversation. My name's Shari Ling, I'm a geriatrician and rheumatologist and internist still practicing within the Veteran's Administration Medical Center and I'm actually delighted to help address this issue and provide the SEMA's perspective. Dividing this into really two parts, one is using data to accelerate change, specifically using Medicare data to accelerate change and then subsequently to address briefly the future of measurement, improvement, and health system innovation. And very excitingly just listening to some of the conversations this morning these are the right conversations, the hard questions that are being asked about the use of the data, what do the data mean, and how do we actually drive towards what we all share to be a common goal.

And starting with that, we did open this session with driving towards something that we all believe is important to remain focused on and that is improving outcomes for the beneficiaries that we are actually privileged to be part of the care for. So just by way of perspective and scope CMS remains the largest single payer for health care services in the US. Two point five billion claims submitted annually and each one of those can be looked upon as a data point, data points for people who receive the care. The sources of data by and large have been administrative in the past but are really expanding in form and depth, new data sources on the way including electronic health records, encounter data, health insurance exchange and Medicaid expansion data.

Billions and billions of non-claims data that are, that we are building upon from all and each care setting where people receive services that are paid for by Medicare and Medicaid. We are thus transforming from a passive system or just a repository into a active purchaser and a vehicle of change, change towards improving outcomes. So how do we and what are we doing to transform the approach to data across the data life cycle? How are we, and CMS is embracing a new culture of data, data as a vehicle to improve. This includes establishing a strong data governance body and practices that really are promoting enterprise wide thinking on how to improve, how to use the various levers that we have at our disposal to improve the quality of care, improve the health of the populations, and also reduce costs by way of improving quality.

Employing advanced data analytic techniques to not only ensure high quality data but also how to use those data in way that is quite actionable. There are new policies underway to support external uses of data while maintaining appropriate beneficiary privacy protections and also

expand internal use of data and analytics to inform policy decisions, decisions of quality, of public reporting and also to prevent fraud in a data directed, data driven manor. So part of the effort is to improve the data governance at CMS and this is something that has been embraced across the agency from data collection to data dissemination and part of this is also not only expanding the tools that are utilized but to give further thought on how the data could be used in a way to best improve health outcomes for our beneficiaries. Some of the data dissemination activities include use and availability of data for accountable care organizations again to drive improvement, quality improvement organizations researchers states demonstration projects innovation center awardees all in all again focusing on data, making data available and useful and actionable to drive towards improvement.

So just one such example is CMS is sending near real-time data to Accountable Care Organizations for patients enrolled in the ACOs again, this includes administrative information, the patient's claims histories, all types of services that have been provided to a given beneficiary under the auspice of the Accountable Care Organization, the type of procedures and supplies, and this is a tremendous opportunity for the private sector to partner and help ACOs transform those data into clinical information both of which then can become actionable.

One important product of this effort and focus on information has been that of the Blue Button project and product. The VA, the Department of Defense and CMS have collaborated to give patients mechanism to receive, download, and share their own personal health data including outreach to some 300,000 beneficiaries thus far. This is again a tremendous opportunity to not only identify and use a new data source that is of patients but in a way that is meaningful to patients, about patients, and will permit them to engage as partners in their own healthcare. So how this actually can interface with existing infrastructure is something that is highly desired, and again this is a huge opportunity for the private sector to help facilitate and our systems to embrace.

So we're in the process of healthcare transformation from the state of producer and provider, centric care, a system that has been driven by volume as opposed to value, a fragmented system of care where providers in the out-patient setting don't necessarily speak to the providers that assume the care of their patients in the hospital, in post-acute care. There are many post-acute care settings now that are part of the system and this has all been quite a fragmented system and process and difficult for patients who need to traverse from one provider to a next each time information not being transferable or transmissible. The system transformation is underway in parallel with private and public efforts underway concurrently towards a state where care can be more person centered, outcomes driven, coordinated, and also includes and builds upon new payment and care systems that I've depicted here.

Now is there evidence that this is working? This is one such graph, I should have also brought the cost graph along with it and also a graph of infection rates across the country. This is one graph of Medicare all cause 30-day hospital readmission rates from January 2010 to January 2013. And as you can see for the first time over this period we've actually been able to reduce the 30-day readmission rates. Why is this important and how did this change occur? So why it

is important, it's because it's about patients who are admitted within 30 days of being discharged from a hospital. There are many reasons which included are technical reasons for a need for readmission, they're also breakdowns in communication, lack of coordination, lack of standard known processes that can help successfully discharge patients to their homes without needing to be readmitted and certainly post-acute care providers now are looking upon themselves as part of the solution to this problem.

So this actually was achieved using multiple levers pulled concurrently including the partnership for patients efforts which enlisted the help of networks of hospitals out there. Quality improvement organizations that likewise enlisted the assistance of communities to not only use data but also provide technical assistance on how to successfully discharge patient while lowering their risk of readmissions. So, and also making note of readmission rates on public compare sites was part of the solution as well. If you would actually look at the cost curve the rate of growth of cost this too has trended in the downward direction as has the central line associated bloodstream infection rates which again reflect a focus on data use of evidence based practices and spread of those best practices in a way that is a technical solution offered at the bedside to again improve patient outcomes.

Briefly Sam had mentioned earlier some of the innovation center care models. These are, this is just a summary of combination of models of care and also payment models looking at innovative ways to improve outcomes while also curtailing costs through quality improvement. Some of these focus on bundled mechanisms of payment; others are really focusing on synthesizing care so that primary care is more seamless again and is in a system that is better coordinated. Other efforts including the partnership for patients I've mentioned and community based care transitions and Million hearts focuses on outreach to communities, technical solutions, as well as making data available at the site of care where patients are seen.

So the future here lies in focusing on data, aligning data, and measurement strategies in a way that can be synthesized for patients across care settings. This will require standardization and focus on data elements that matter. So what would help align these measurement and data strategies across all care settings, that would be the national quality strategy and importantly patient centered care is a key domain as is improving health outcomes through appropriate clinical practices at the site of care.

There are tremendous opportunities here to build a system that is iterative, robust, data driven. The same data that can be used to improve at the site of care can also be used to create evidence. Evidence then can inform treatment and policy decisions and also can be incentivized if not supported in novel payment constructs.

So I will stop there and thank you for your attention.

Stephan Fihn: Good morning and thank you. One of the advantages of going later in the conference is that we have the opportunity to build on some of the key theme and I will try to do that by example. For those of you who were here yesterday had the opportunity hear from Drs. Bob Jesse and Terry Cohen who described our systems in some detail. So I'm not actually going to reiterate that but to really drill down and talk about how we are presently trying to employ the data systems to both evaluate and improve both cost and quality. So you know we've heard to some extent about sort of the limits of what we've got in terms of data systems now and from a healthcare perspective I won't go through it in detail but I think one of the big themes is that we actually collect and store huge amounts of data. We analyze a little of it and use an even smaller proportion and we're trying to move more to the right on that continuum which Shari just actually described.

And we do a lot of trending and rule driven reminders as a health system we've got very limited and developing capacity for patients and a retrieve and manage their own information which you've heard about. And then in terms of how we, what we do with our data now, Terry Cohen did describe the large corporate data warehouse in which we've tried to bring in essentially 20 years of data that we've been collection on 20 million patients. And what we do with it mainly is our office produces about a thousand data products right now and as you can see this is one of our web based menus that span from business operations, clinical care, quality performance, special programs, workload, et cetera. And in fact we've got so many of them and each one of these products might be a very large ProClarity OLAP cube with drill down to patient level that may have thousands if not millions of patients in it or at a provider level.

And we've got so many of 'em we now have to have a Google-type search engine for people to find the data 'cause their most common complaint to us is they actually can't find the data that we produce. And we've heard also today about the notion of how do we get data to individuals who need to make decisions at the point of decision making as opposed to a complex cubes which have to be downloaded into Excel spreadsheets and make their own pivot charts or even looking at retrospective data that is difficult to, so then incorporate into current practice. And so this would just be a typical data product and many of your systems probably produce these and I think they do have value at the programmatic level but again we're trying to say how do we actually deliver data that will influence how people both can summarize and use data. So we're, one of the strategies is data aggregation and we all know the dangers and the difficulties in aggregating data but we have close to 1200 system-level performance measures.

So the question from our clinical executives in our leadership is how do we make sense of this, so this is one example where we try to summarize vast amounts of these performance measures in a single graphical representation that tries then, these actually have drill downs so they can actually click on these and drill down to facility levels and even deeper into their organizations sort of as diagnostic tools to begin to think about how are we doing. So for this

particular medical center you could see it looks like they're doing okay with heart failure patient satisfaction but the red dots up there with their AMI mortality or their employee satisfaction identifying those as areas that deserve perhaps some increased attention. One of the big problems we're also sort of coping with and we've heard that but you know just to reemphasize sort of the vast data streams that are beginning to appear for which we are not prepared to deal with and we've heard about these that the patient devices, every monitor that we issue to a patient basically now talks, has a chip in it, can be interrogated, C-Pap machines, blood pressures, cuffs, monitors. We're installing all sorts of real-time information systems in our ICUs, our operating rooms et cetera, we are RFIEDing all kinds of equipment and ultimately patients and employees and suddenly we've got these massive streams of data, some of which are generating gigabytes per hour and we don't really haven't coped with the idea of how do we, they're very valuable at point of service but then to extract the value from these systems for, as learning and understanding both, and evaluating how do and sort of the feeling we have right now is that we're gonna drowned in data unless we sort of start to figure out how to make best use of it.

Bob Jesse yesterday went through a lot of the, sort of the big data applications and I won't go through them again and I think Brent James sort of summarized 'em, but I'm gonna present a couple of examples in ways in which we're starting to sort of use our data to we hope improve and evaluate care. So, and we've deployed a patient centered medical home model throughout our system at 1,000 sites of care about 6.6 primary care patients and as many health systems we've sort of figured out or trying to figure out how we manage those very complicated patients that we just heard about the multi-morbidity patients that we were advised to think about as INNOV1s or small, small diseases. And one of the issues and most, I suspect all of you, associated with health systems have tried to develop some tiering mechanism to identify those high cost, high risk patients and we heard about the readmissions. In our system what we've tried to do is leverage all our clinical data and as well as our administrative data to improve those predictions.

And so if you for instance know a little bit about prediction we evaluate prediction models with area under the curve C statistic where one is perfect, zero is wrong every time and point five is a coin flip. If you look in the literature most of the models which are being used for tiering in health care systems have C statistics of about point six, some as high as point six five, there was a recent review that for instance for heart failure models. We have tried to then pull in data from all our systems, from the corporate data warehouse from multiple domains to build models and as you can see here using that approach with about 120 separate variables we're now able to generate C statistics that approach in some cases, for instance if you look at these are for predicting death within 90 or days or one year or hospitalization or the conjoined probabilities of C statistics to point eight to point eight five and our latest models are pushing point nine.

So very high ability for prediction using these large data systems and if you look back here there are predicted to observed our OE ratios and you can see they're very close. So these models are actually very accurate and we validate them year to year and as we break these down say into categories of five percentiles you can see the ranges that we're able to get and in fact if we

now, and this gets to that sort of rare disease, start breaking them down into even percentiles of patients you may say one percent, but for us that's 60,000 patients in each percentile. So you can see in the highest percentile we've got patients who are 70 percent or so likely to be admitted or die within the next year, they're extraordinarily high risk and then we know who all those patients actually are. And so we then actually run this model every week, we publish these data on a website that's available to primary care physicians, we've now done this for two years, this is my patient panel that lists the patients each week, updated from highest risk to lowest risk and actually then tells me what programs I might be using for these patients, are we providing the services to them that we have available, Home Telehealth, home-based primary care, palliative care, are they using emergency services, when were they last in clinics. So to, and we try to get our primary care teams to review these data and ask are we coordinating care for these patients well. We're actually now as of, as I speak, releasing actually a web application for our RN care managers, one of whom's on everyone of these 7,000 teams that then integrates all the data from all the sources and tries to help them use this risk data in coordinating care for these very high risk patients.

And so again you know I think for me the idea is to sort of move from the notion of big cubes down to data delivery at the point of service for high value data that can be used for patient decision making. We can also elevate that and then look at where the geographic distribution of our highest risk patients are and from a leadership standpoint ask what services do we have in these geographic areas where these patients are living and are we serving them well. We're now moving into trying other predictive equations such as kidney injury, likelihood of C-dif, or MRSA, and what is particularly assailant to us is trying perhaps to identify patients at risk for harming themselves which is a major problem that we face and does DOD and working with some high level knowledge engineers to try and do that. Another way in which we're trying to aggregate the data is this is the menu of laboratory tests that I see whenever I open our record and it looks just like the paper list that I've seen, I used to see 30 years ago with a few exceptions.

What we've done now is rather than present a vanilla list we've analyzed 30 million records over 15,000 conditions and 10,000 orders and tried to ask the question you know, could we present a list of tests and therapies based on the patient so this is the Amazon models people talked about yesterday as for doctors who've seen patients like this the last 10,000, here's what they ordered, we're not telling you to order this but you can see. Now obviously Amazon does make mistakes and you know we expect the physicians to exercise judgment, these aren't guideline driven, these are experientially driven. The last example I want to talk about is using our data systems to evaluate and to look at costs. So we've taken data from surveys that we do of providers, from our corporate data warehouse, from our CAHPS data, and put together an index that tries to look at how well our 1,000 sites of care have implemented the patient centered medical home and you can see we've used 53 items from our data systems to do that.

What shows here and this is a little complicated, but just to, we then can look at the highest to lowest scores and then ask the question are they doing, is there a difference. And you can see at the top row of these PI^2 scores there's to the bottom, they're big differences over a point in

CAHP scores, you know which is, for those of you who know CAHP scores and try to improve them in your medical center, a huge difference, provider ratings, and in provider burnout. So gigantic differences across our system so we're now trying to focus in on those places that do it well and those are implementing it less, we've also seen significant reductions in admissions for ambulatory care sensitive conditions at the sites that have implemented well versus those that haven't. And you can see here, this is just all the performance metrics with the right side being the high implementers, the left side being the low implementers, and the difference in those measures and you can just look visually and say these places that have implemented this system are doing better on a variety of systems and what we've got to learn now is what has made those better implementers different. We've also looked at return on investment and shown that our ROI's better at those places, too, so I won't go through the concerns and challenges again, Dr. Jesse mentioned many of these but I think we're beginning to try and leverage some of these, our big data into specific ways to improve cost and outcome so I'll stop there. Thank you.

John Supra: Thank you, and as we're looking at this book *Metaphor*, I'm gonna take the time now to step a little bit away from what's going on at the clinical or frontline level and start to look at what goes on at the state Medicaid level. And as I put this together a couple weeks ago I didn't expect we'd be in near freezing temperature in D.C., and it was a beautiful fall day in the Carolinas but I think even more importantly it's another metaphor like that art that was shown in the session yesterday, it's a metaphor for the complexity of data. What is the nature of the Medicaid data, how do we use it and why, and what does it start to tell us about what we need to do as we shift and change our operations at the state Medicaid level?

So in the Medicaid program our history has really been about policy, development, and operations. When I talk about policy and operations, determining eligibility, who is in or eligible for the program, how we make those determinations, and what those associated operations are, and we've been primarily in the claims payment business in Medicaid organizations. How we pay, what we pay, primarily fee for service payment, and we'll talk some more about that, and the value or importance of the program was in making sure people got paid and not as much about what happened to the patients, what did the program mean in our communities. And our data use historically in Medicaid has been really focused on reporting, a lot of requirements by CMS, a lot of state programs that had requirements. But I think more importantly the reporting's been after the fact and I think Shari talked a little bit about the use or the speed of encountered data.

In our state and I think we're probably pretty average, our encountered data comes into the system and we do very little with it beyond counting, making sure the providers, the members, are who they say they are, but we're not doing as much as we could with them. And in South Carolina, and I think this was similar to the CMS perspective, we've really over the last two years shifted our mission and our goals away from just making sure we operated efficiently to really thinking about how we purchase the most health. And then it begs the question or requires the data to support what is health and how do we know we're getting a good value.

And I think in a previous session there was a lot of, I think Paul was talking about that shift from volume to value.

And in doing that I think it really pushes Medicaid organizations, state health organizations, to really think a lot more about population health in a very different way. And how do we figure out if the investment that goes into the Medicaid program, typically the largest program, along with all of the other investments in public health dollars are yielding the outcomes we're looking for. And in order to do that effectively we need to collect and understand the data, we need to use that data in our policy decisions. So we've heard a lot about, in the last two days, shifts in payment methodologies and I think the question, the woman that asked in the previous session from I think the New Jersey Quality Organization, we need to continue this movement from primarily fee for service. And although many states, many of the health plans have started that move toward some incentives, started that move towards measurements have used those outcomes. I would argue and very much agree with her, we're still very, very far away from systemic change that drives a shift away from volume toward value and quality. And we need to continue that move and in our state for example, we have a number of very innovative projects going on, but they're not systemic, but I think even more importantly the most successful ones end up with our health systems getting less dollars from our Medicaid program to do exactly what we want them to, and I'm gonna give you two examples. One of our systems realized that if they took the EMS time that we're out in the community and stopped the houses and the homes of some of the highest ER utilizers, they could save trips to the ER. Well their ER or their emergency department ends up with less Medicaid revenue and we're not doing anything to help them understand that that's a worthwhile program and how do we incentivize it. In our Charleston area in South Carolina we have a number of EDs very close together so we have a Medicaid population that moves between them. So they looked at how they used HIE, Health Information Exchanges, within those EDs to ensure that they're not repeating tests that were recently delivered.

And I think in the previous panel they talked about some of the differences in populations, well they've learned that the Medicaid population is highly transient among those ERs and they were able to save money that will ultimately accrue to the state and the federal government. How do we shift our methodologies to recognize that in payment? And we need to work hard, and I think you saw some of this as we we've talked about what's going on in individual provider practices, what's going on in health plans like the WellPoint activities, the Optum, the United activities, and what's the role of state Medicaid to understand where in the process do we want the connection to the patient? Do we figure out how to assess, use predictive modeling like the work going on in the VA, to figure out who is at-risk and then invest in the right incentives? And I think we're gonna need to think a lot about how that change in payment, payment methodology in that relation happens in order to get where we want to go.

And then finally what is the state Medicaid or the public-side, the state-side role in transparency when it comes to cost and quality information? And we know that CMS earlier this year put out some comparative cost information within the Medicare rates and programs and that's a step towards transparency. So as we talk about what goes on across the medical practice

community we need to think about how we then deliver this to our citizens in the broadest sense and I think even within our Medicaid populations have greater challenges in making meaningful information about cost and quality transparent. So over the years, I'm gonna show two slides about what I would call traditional analysis of our Medicaid data. In this first one I want to talk a little bit about is the fact that we know in our state that Medicaid alone isn't enough. And what this is, is a state-wide map that shows a collection of chronic diseases for adults, people that currently are Medicaid recipients, and you see the blue areas are people who are generally healthier relative to that basket of chronic diseases, and the more red areas are people who are unhealthier.

Well what this says from a Medicaid policy perspective is we need to find ways to drive different benefits, different benefit design, and more flexibility to those that need more care or different c are. But what it also tells me is something we generally know, we know that in the state that that area of our state suffers from endemic poverty, generational, and we know that our educational outcomes aren't as strong. So what does that start to tell us about policy and I think we saw earlier and we've heard a little bit, what does it also say about where we put our state or public investments relative to what have generally been called the social determinants where education, transportation, housing, and health are all interrelated? And we hear this in some classic examples of as physicians, able to prescribe drugs and pharmacies, but difficult to prescribe things like air conditioning and vegetables. So how do we start to think about this and what is its role when we look towards value in our system? Another example and as you look at this, we've done some work in the state of South Carolina relative to birth outcomes. We identified that we were a state that had a very high amount of pre-term elective deliveries, a little over ten percent, much higher than national averages. So we in collaboration with our hospitals, our birthing hospitals, our association, a number of foundations, we really looked to bring that rate down.

And this is, again interesting, traditional analysis that brings together or marries location, number of days in the NICU, the different levels of hospital, what care is available, different types of prenatal support programs, and it's interactive along with income which is really interesting. But part of our challenge in Medicaid as I said at the beginning is this is data that's now over a year old, it's data that took a long time to pull together, it's not timely, it helps us drive policy, but it doesn't get at the day-to-day operations that I think many of the of the systems are working on this are able to do. So it asks the question of what is our Medicaid organization need to look like in the future. Well I think we've heard this across the spectrums of speakers in many of the presentations, we've got way more data than we use. The challenge is how to bring those multiple sources together and how do we as a state Medicaid organization and those in the public sector really facilitate that? And likewise and I think most important from where I sit in a Medicaid organization is, how do we speed up or accelerate the time to use the data available to us?

How do we find that velocity or flow of data? I spoke of the encounters earlier and Shari talked about the encounters relative to some of the CMS programs, my staff and team see those a month after they happen, we don't do much with them. Our claims data we focus on paying it,

we don't focus on what it tells us about what might be going on in our program. And as we started to reach out to some of our other research teams within the state that are particularly working on social media data and how to use that in a broad sense they started talking to us about the shelf life of data. At what point does the data become less than actionable? What time is it too late?

And then finally and I think we've heard a lot about and I think the work they're doing at the VA to connect disparate sets of data. How do we find those data sets that matter, what is our role in the public sector to drive some of those connections? We've heard a lot about all payer claims data bases in many states, and they're helping to move the ball forward, but how do we connect those data that appear to be unrelated, that may not be what the state Medicaid organization has traditionally thought was within their organization? And in doing that I think it begs the question about what do we need to do as leaders in the public sector, Medicaid public health organizations, in order to drive this change so that we can participate with those that are doing very interesting things at the front lines in the clinics, in our EDs, and to participate with the health plans that are often managed care in many states? Well one of the first things that we've talked a lot about in our state and I think across Medicaid organizations is our capacity to do this type of work. How do we drive intellectual curiosity? We talked a lot about it in these sessions, analytical, research, research-focus, how do you drive that into the public sector and how do you drive the expertise and skills, not to solve all the problems but to make those connections and bring the right people to the table? And then what system and tools do we need in order to do this or facilitate it? I think Paul said earlier, he was talking about something that was very 2005, most of the tools we work with are sort of circa 1980. How do we move that forward? How do we drive from a leadership that vision and how do we then ultimately drive a culture and mindset that is data driven within the public sector?

And from where I sit that's gonna be a hart set of changes but we need that in order to take the Medicaid programs forward. Now there's a lot of interesting things going on, I just came from the Medicaid Directors' Conference this week as well and we have states doing interesting work. Oregon is trying to drive value-based funding and flexibility working with CMS, and in Arkansas they're trying to push that modernization of payment methodologies forward. We're gonna need more of it but we're gonna have to drive it not just through our leadership in states but through how we operate. I've also found too with the public sector, our staffs are generally not comfortable with taking directional information and working and iterating through it, trying to figure out what do we know about this data, what does it tell us we should do? I often hear about well, we can't do much with the claims and encounter data because it's really dirty especially on the first pass.

Well we know that, the commercial health plans have been working through this and we need to think more like that. We also need to think about what our role is and how we partner with our health plans. Many states at the Medicaid organizations are moving away from simply being the fee for service payer, but moving towards managed care relationships. But I'm gonna argue those are really still in version one because most of those then just ultimately pay fee for service. How do we change that relationship so that we in the Medicaid organization

understand that our job is to manage those managed care relationships? And then finally I believe that often states look to RFP or purchase systems or tools to buy their way out of that problem and I don't think that's an answer. We've really, and both our state as well as I think other states, we need to take more ownership of the technology and some of the expertise and be a partner working with innovative health plans, working with our most innovative delivery systems.

So what are we doing in South Carolina and what do I think states across the country need to be doing? Well first of all we do need to upgrade our systems. Some states have upgraded, others have not, but I think more importantly and in South Carolina we need to think about our operational side of our business not from the claims payment, but what the encounter data tells us, what the other data might be telling us. And we're trying to build an operational data store that isn't about policy and research but it's about running our program and not just by paying claims, but managing our managed care organizations, participating in the assessment of those people that might be at highest risk and might need special interventions. In Medicaid you know the gorilla is the MMIS, it's typically, it stands for Medicaid Management Information System, typically referred to as the claims payment part of Medicaid. We need to think less about the claims operation and a lot more about those data sources in the flow of data and we need to explore data sources that tell us about those social determinants. We're working with one of our universities to bring in more social data. What does it tell us about our operations if people in this social media world are talking about the challenges of working with the Medicaid organization wouldn't I want to know about that? And we need to employ new analytics working with partners as we build expertise.

And to really finish up I want to talk about this idea of context. We've talked a lot about different measurements, standardizing measurements. We hear from the people, the clinicians in our state that the more we can standardize the measurements so we're not asking for specific ones in Medicaid, specific ones for Medicare, specific ones for other health plans, it's helpful. Well as somebody said earlier today, the rubber hits the road when it comes to payment. Well when we continue to pay in one way that's what the clinicians are gonna do, that's what our health plans are gonna do. And I'm gonna argue that our policy and research and analytics have had a history of being interconnected, probably a little slower and not as quickly as want.

But we need to think about our Medicaid organization in a much broader sense taking it form a research and analysis that I showed you some great examples of in South Carolina and how that interacts a lot more quickly with policy development, but we also need to think about our operations. What are our key metrics? How are these interconnected most importantly to patient experience and our customer service to our provider experience, 'cause as more people have choices and access keeping providers in our Medicaid program is gonna be more and more important and we need to be a payer that is easy to work with. And that's part of the transformation that I think Medicaid organizations need to do as we participate in driving cost and quality towards value and away from volume. Thank you.

Nirav Shah: In August of 2011 Hurricane Irene was barreling toward New York City with 120 mile an hour winds. We were told that there was gonna be a 20 foot storm surge and all the nursing homes, unfortunately many of them are built right along the water on Long Island, were facing a 20 foot storm surge and had to evacuate, dozens of nursing homes. It was a weekend. And last I checked most government works don't work on weekends, but what we had done the month before was we had published on our website, in a nice format and told everyone it was there, the most boring data set ever, the weekly nursing home bed census data. And the operators knew about it and on that Saturday and Sunday they looked up that bed census data and moved thousands or patients out of harm's way to friends who had vacancies, on their own.

It was a success and we learned from that and said, Todd Park, teach us what you've done at the Data.gov model, you know Greg Downing help us out with Socrata, let's do this statewide, let's do it for all of our 300 data sets. We publish baby names, people love, that is still the most popular data set, where people trend how Brittany goes up and down over the years, don't ask me why. We published all our restaurant inspection data and Yelp has called us up and they're gonna take it and put in their ratings for all of New York's restaurants. We published our student BMI data for all 680 school districts where we have why is Niskayuna a 10 percent obesity rate and across the street at Albany Central Schools they're 25 percent? And we've got dozens of incredible stories about the school lunches and the programs and the activities and what the vending machines hold, all for free by publishing all this data on a nice website where they can do graphics and they can geo-code the data, they can do all these incredible things.

And for the department, so we helped our citizens, we helped our nursing home operators, we helped ourselves because in the first three months alone we got 700 fewer Freedom of Information Act requests on a base of 5,000 a year, so that, so, people inside said, "This is a good thing, we need to do more of this." But this transparency thing is not new, you know it was over two decades ago that New York State first published in the Department of Health the volume outcomes relationships for cardiac surgery. We knew and again, that was a Freedom of Information Act request that published all the doctors' names and a bunch of doctors went out of business and everyone else improved, so today our cardiac outcomes are among the best in the country as a state because of that transparency. Everyone said patients would use that data and not understand it, patients don't use the data, it's all peer pressure.

And two years ago we said in PCIs, Pericutaneous Coronary Interventions in New York State, fully 23 percent of elective PCIs done in the State of New York were inappropriate according to national AHA/ACC guidelines, it's a 20 percent blockage, they're putting a stent and a balloon in. Well you know, they must be right, right? Well we just published the data, gave it to the providers, gave it to the hospitals, today that inappropriate rate is gone from 23 percent to 8 percent. I didn't withhold a single dollar though I threatened to, maybe the threat helped. And it is the nature of transparency is changing, too. In April of 2012 a 12 year old boy, Rory Staunton who cut himself in the school gym ended up dying of sepsis at one of our premier medical centers, preventable and it's a complex systems problem. ICU say it's not our fault, look at the

wards," the wards say it's the ER, the ERs say the lab didn't get us our lactate levels faster enough, everyone points fingers, it's a complex systems problem. And yet we know from Kaiser that using simple evidence based protocols for the early detection and treatment of sepsis can reduce deaths from sepsis in the hospital, the number one killer in hospitals today by 30 to 60 percent. So the state decided to mandate the use of these protocols for all 220 hospitals in the State of New York and as of January 1 they will all have evidence-based protocols and we estimate conservatively that 8,000 lives a year will be saved that were needlessly dying from sepsis and it was all about data and transparency.

And it's hard work, common definitions of sepsis, what is the parsimonious data set that you need to get, what do they need to report, how do you severity adjust, how do you report back, how do you keep a safe space for hospitals to learn how to improve their data before it becomes Freedom of Information Act, free to the public, and you're dinging people who don't deserve to be dinged? It's hard work. We've learned though that data can help solve those complex systems problems and it has helped us in our Medicaid program achieve a vision of the triple aim. You know in Medicaid in the Department of Health, 40 percent of the health care spent in New York is Medicaid; it was a $54 billion juggernaut growing at 13 percent a year when we started. Three years ago the governor Cuomo put a team together and said, "Figure it out, fix it, or else." It worked. Overnight we changed the growth rate from 13 percent annually to 4 percent and capped it there. We saved $4.6 billion the first year, are on track to save $34 billion in five years.

We've asked the Feds for a $10 billion waiver as a result, a Medicaid waiver, if you want to approve that any time we're happy to get that. But it wasn't rocket science, it was using the data, it was using the claims data set that we have in Medicaid and saying, "Maybe we should increase that generic substitution rate," that saved us $425 million a year. Maybe the nursing homes are calling pressure ulcers grade two and it's different than stage two in the hospitals, there's something going on here, we put out $1 million toward a learning collaborative, that saved us $28 million, not to mention reduction in pressure ulcers. Maybe we shouldn't be paying for growth hormone shots for idiopathic short stature which costs tens of thousands of dollars to the Medicaid program and was part of the benefit who knows why, and it would result in, because it's "idiopathic," these people have normal growth hormone levels, it would result in kids who end up being five foot five, being five foot seven, and I don't see any benefit of that, we saved tens of thousands of dollars for that.

And yet we weren't paying for things like USPSTF Grade A and B recommendations, so we started covering that, we save money on one end, start paying on the other end. We did a study where we saw that today Medicaid pays $755.00 a day for an inpatient stay, $429.00 for an inpatient psychiatry stay, about $300.00 a day for a nursing home stay, the state pays about $129.00 a day for jail, $68.00 a day for a homeless shelter, and $48.00 a day for supportive housing. Housing is healthcare, who would have figured, supportive housing with a little behavioral health services, some substance abuse treatment in the basement, is the right thing to do, it saves money, it improves outcomes, and so we asked for a billion dollars from the Feds to help support supportive housing in our waiver. Of course they came back and said, "No,

CMS doesn't pay for bricks and mortar or capital, it doesn't make sense, we're gonna refuse that." Of course they're willing to pay for that if it's called a nursing home and keep people, I'm sorry, I had to make that jab, so you know, we get it, and so we're putting state share dollars into supportive housing, hundreds of millions of dollars committed into supportive housing 'cause housing is healthcare and we have the data to see that in real time. The 550 problem, the 5 percent of patients who cost 50 percent of the healthcare spent, you know, how do you coordinate their car? Well my monitise, in their Regional Health Information Organization, their RHIO, has clinical data, and on top of it they've built a nice system for community healthcare workers, navigators, social workers, other people outside the clinical team, to access that data and they can see Mrs. Jones has CHF, asthma, hypertension, but they can add to that record and make a parallel problem list.

So Mrs. Jones, number one on her problem list is domestic violence, number two is unstable housing, and if you're looking at why she's actually being readmitted seven times a year, it's not because of that problem list, it's because of the other problem list, it's those social determinants, it's public health, it's all the things that we as a healthcare delivery system are very good at ignoring. We have realized that building on top of that infrastructure is gonna be fundamental, that data from electronic health records is going to be a grade up from the claims data. We've done a lot with the claims data but we're hitting a wall, we need to get to the clinical ERH data so we're investing in a statewide network from Buffalo to Brooklyn. You can pull up anyone's medical records, we've created an intra-operability workgroup with 19 states, 21 EHR vendors, 22 HIE vendors, and as of tonight it'll be the country of Ireland, will Ireland will sign on and then Denmark and others. And we're setting standards that the ONC has not set on intra-operability because we need it and we can't wait anymore.

And as a result this statewide network, what would you do if you had all the data that was clinical and by the way we'll have an all pair claims database funded by our exchange establishment dollars up and running by next summer, for 19.6 million New Yorkers, what would you do if you had all the clinical data and all the claims data and because trust me I'm the government, I can marry that together, and free it? What would you do? Well, I don't know what I can do, I know I can't do that much, but I know that a lot of people out there who can do a lot more. Many of you read that *Time* "Bitter Pill" article, you know CMS released 100 conditions worth of data, great stuff, scratching the surface. Next week I'm gonna release 1400 conditions, cost and charge data for over 200 hospitals in the State of New York.

Why does it cost $4,000.00 for a c-section there and $12,000.00 for a c-section there across the street when the quality is the same? I don't know, I'm just releasing the data. I may lose my job for that, but that's all right. So I've seen companies today, you've heard what we are doing today with big data and small data. I've seen Oscar, one of the insurance plans on the New York exchange marketplace; Oscar can map the efficiency and the effectiveness of care at the provider level. So using the data that Dr. Triola used, our Sparks data that we released on our website, they can map out that Mrs. Jones is best treated because of her conditions by Dr. Smith because Dr. Smith has outstanding diabetes outcomes and lowest cost and speaks the same language, and so the narrow network of tomorrow is an INNOV1 for Ms. Jones, that's

happening today. You know we've done a fantastic job creating a $2.7 trillion healthcare delivery system, it's a perfectly designed healthcare delivery system, perfectly designed to deliver more and more healthcare. Well we've forgotten is what people really want and it's more and more health and so we need to figure out how to change that healthcare delivery system to deliver more and more health and I know that we are already well along the road and from what I've heard today I think we're gonna get there in our generation. Thank you.

Robert Crane: Well thank you to the panel for some great presentations and a panoply of ideas here. Steve noted that we collect huge amounts of data, we analyze some and we use little. Well I think the panelists actually have shown us a lot of use in very interesting ways. But I'd like us to look forward. This is the 20th ECRI policy conference. Let us assume that we're back here talking about this topic in five years. What would each of the speakers like to be telling the audience that they've been able to achieve or that they want to achieve between now and then on this topic. Who'd like to start.

John Supra: In five years, I would like to see a delivery system that is very focused on our patients and a funding model to that's fundamentally shifted towards value that allows us to pay for housing. That allows us to figure out how we combine our social benefit dollars with our health benefit dollars so that we get out of the system value in bringing this country, the citizens of South Carolina to a place where we are the healthiest nation in the world.

Robert Crane: I'd invite people to come to the microphones too as we continue this discussion. Who's next?

Nirav R Shah: So I agree. I think we so often lose the patient voice. We don't actually listen. When we talk about patient reported outcome measures we're actually talking about expert defined patient reported outcome measures. Not patient defined or patient reported outcome measures. So to the extent that we are not delivering what patients want, what our clients want. What we ourselves deserve. I think that we will see that just by getting out of the way if we are government or facilitating things. Letting the private sector and the innovation of incredible young, smart people do what they do best whether it's in at NYU or Oscar or in many other places around this country. And within five years we will be there. We will have a health system not a healthcare delivery system.

Shari M Ling: I'll go next. Within the next five years, hopefully within the next three years we'll have a meaningfully implemented system that focuses on

quality with alignment of what quality looks like. I think we will also figure out how to and what those meaningful outcomes are that our systems should drive towards. That necessarily includes and starts with the patients, with people. So part of this will be figuring out how and what that data source will look like. It is an expectation in the clinic that is often difficult to operationalize when it comes to large systems. So flexibility must be retained and maintained. And I also think part of our focus which is achievable will be to develop those partnerships. It is silly for us to all do the same thing in the same way to try to achieve outcomes when in fact we can play to our strengths as individuals and the strengths of our partners that is synergistic rather than duplicative.

Stephan D Fihn: So if we're going to blue sky here. You know our system is really focused on a mission. We have a population that we serve and we are dedicated to the service of veterans in specific. And I think where we're trying to move and I would hope we're there in five years is one to sort of step back as people have heard that we're not bound by payment systems but we still are a largely and encounter based system, to step back and be able to both measure and decide programmatically and act at a population level that will improve the health. And I will say to Nirav we will have to figure out how to define that. But I think from improving disease to improving health of the population that we serve and that in doing so we are able to both gather and to incorporate and satisfy the individual needs and preferences of people that we serve. And I think the challenge for us will be that we're back to that triple aim. I don't expect our budgets going to be a whole lot bigger in five years from now and so to do that with the resources that we are given to provide healthcare as well as housing. We do housing and we do education. And we do the other big piece that actually I have not heard at all in this conference which has sort of surprised me, is mental health care which is in our population is probably as important as the other forms of health care that we deliver and to do that in a thoughtful and integrated fashion.

Robert Crane: So Jeff you have a session for 2018, Big data's influence on health. Right. Let's take some questions here.

Barbara Rebuild: Thank you I'm Barbara Rebuild. I'm the Director of Operations for Ecri Institute patient safety organizations. I want to keep with Bob's point of let's stay focused on the future. However throughout the conference there's been a theme of the resources that we need to do all of this. And then I'd like to hear from each of you who have been in the trenches dealing with the data. What kind of technology resources do we need and maybe even new developments to program all of this to make sure

this data is interoperable to bring together and be able to collaborate and create these huge data warehouses and data marts?

Robert Crane: Who'd like to start?

John Surpa: I think we've both heard and I would argue that we have the data and the resources available and I think we have more than enough technology. I think the notion of innovative and thoughtful people. It really is about letting that data flow. Figuring out where the connections are that are going to lead to what health really means in the health value. So I think we have most of it and I think we've heard that. It's a question of finding those innovative projects that can make those connections and then to figure out what we want to measure and what the outcomes we're shooting for are.

Robert Crane: Anyone want to add?

Stephan D Fihn: Yeah. So I'll second that. And actually if you know the answers to those questions I'd love to talk to you after this session because we struggle with the issues of data, what I would call integrity. Is it valid, is it reliable, is it right because a lot of this real time data is a lot messier then what we've been accustomed to dealing with. We get the value of all patients and in near real time but we sacrifice I think something in sort of our understanding those sort of data elements. The technology is something I'll be clear we're struggling with. John mentioned you can't RFP your way out of this so increasingly the expense of maintaining servers and even the cloud I don't think is necessarily a solution. I talked about the amount of data. I think these are going to be interesting problems and we can't all behave like the NSA to solve this problem. So I think the industry's going to be, there's going to be collaboration. There are going to be interesting technological fixes and data filters and all kinds of ways to address this. And I think that will be one of the functions of these communities like ECRI and others for sharing not only collaborative data but also solutions for how to manage and use the data and care for it. It needs curation and it needs care and feeding because by itself we've heard that repeatedly here. I mean it's one of the themes of this conference that I've actually liked because so often you go to these conferences and what you hear is just throw it in to a big dataset and use Hadoop and get your answers out. And I think this community is sophisticated enough to understand and deal with data to realize that is not necessarily the solution. So I don't know what the answer is but I

think you've identified a set of problems that really deserve a lot of resource and attention.

Robert Crane: We're getting toward the end of our time. Anybody else want to jump in on that question and then we'll take one more?

Shari M Ling: Sure. So I actually conquer with my fellow panelists that there are technical solutions out there. I think one of the concerns is really quite fundamental. Is that we make assumptions that a given data point means something and that meaning or definition is the same for all parties. If you actually think about it, one example would be disability. So what does that mean to you, each individually. Administratively it means you check the box, right. But if you look at what people and patients and all disease types want, they want to be able to function. What does that mean? That's a far stretch from checking a box of disability. So that's one of the things we need mindful attention to a universal lexicon that in parts meaning to the data that we have. The other is that of culture. So data represent truthful elements. The quality of the data has to be, the integrity of the data has to be held of course to the highest standards. But also what you enter into your data, into your electronic health records has to be complete. It has be balanced. It has to be truthful. And likewise for any research study that is done. It cannot be bias to reflect an assumption that change will always be in the direction of the good. So I think that that is part of the culture that we need to have an approach that we report errors truthfully as well as the outcomes that we desire. That we improve and use every instance as a lesson, as opposed to just reporting what it is that we choose to report because it supports a hypothesis or a message. So that's my response.

Robert Crane: Thanks. A final question before our break.

Gail Hunt: Yeah. I'm Gail Hunt. I'm the head of the National Alliance for Caregiving and I'm also on the PCORI board. I've been here since yesterday morning and what I haven't heard that's kind of surprised me is not just patient centered data being collected but family centered data with the role of the family care giver in both quality, providing quality care and also providing less costly care haven't really been discussed. So I would really hope that in terms of big data and entries into the electronic health record. That we would absolutely include the family caregiver as somebody who's playing a major role in the patients regiment.

Robert Crane: Any comments on that?

Stephan D Fihn: I would second that. We're just actually launching a project now where it's small scale but we've given a thousand IPad's to caregivers because we heard earlier they need access to healthcare data and reporting for some of our most disabled patients. So I hear you. I think that's right. There're challenges both legal and every other sort but I think it's critically important.

Shari M Ling: And I would echo that. We talk about patient centered and it's really about patients and families and you know the work tsunami was mentioned earlier about a data tsunami but there's also one of dementia, Alzheimer's disease and multi-morbid persons who have major disabilities and difficulties for which families and caregivers are a critical solution. So I think that is exactly on target.

Robert Crane: Please join me in thanking our panel for a stimulating discussion.

Jeffrey C Lerner: Well thank you very much and I do think that last question does deserve a lot more thought and we will do that. Okay listen so this is your chance for your break. I would ask you to please really stay on time and remember that last session, you will love it. Be here.

SESSION 8: POPULATION HEALTH, THE CROWD, AND PRIVACY

The boundaries between individual and population health may be becoming more porous as big data takes hold in healthcare. But how is this happening? Much of the data for big data comes from consumers and patients – the target of patient-centered care initiatives – and their experience with the Internet and social media. "Big data" analytics can also rapidly generate data sets to support "in-silico" trials on large

numbers of patients sharing attributes of interest and drawn from multiple sources, such as EHRs and bio-banks. As more information becomes available and is used in various communication and research initiatives, perceptions of privacy may also alter the balance of benefits and harms and affect the future uses of big data. These topics will be brought together to better understand new possibilities for enhancing the health of populations.

Moderator: **Joe V. Selby, M.D.,** Executive Director, Patient-Centered Outcomes Research Institute

William W. Stead, M.D., Associate Vice Chancellor, Health Affairs, Vanderbilt University

Joel Kupersmith, M.D., Former Chief Research and Development Officer, Veterans Health Administration

Jane Hyatt Thorpe, J.D., Associate Research Professor, School of Public Health and Health Services, and Director, Healthcare Corporate Compliance Program, College of Professional Studies, the George Washington University

Ben Heywood, Founder, PatientslikeMe

Joe Selby: As I said, good morning. This is, my understanding is this is the last conference, last session of this wonderful conference and we've focused up to this point on the potential benefits of big data, large databases filled with rich clinical and personal information, their benefits for improving the health and healthcare of individuals, and populations through research and through care delivery, quality improvement, and care delivery. But these data are ultimately, despite where they sit, the property of those individual patients within the population, and the potential benefits are accompanied by legitimate concerns for the security of the data, concerns about breaches of security, loss of privacy, loss of confidentiality. Besides that, individual patients have very different tolerances for these risks as well as different feelings about the use of their data for various purposes.

These risks and concerns have spawned a substantial body of regulatory policy aimed primarily at protecting patients' interests and giving patients the control of the uses of their data. So today we have large patient populations, we have healthcare delivery systems that are poised to aggregate the data and to link it both for research, for quality improvement, and for individual patient care. And we have this large body of regulatory statutes that are sometimes seen as an impediment to doing what the vision holds, what we all see as the vision and what you've heard a lot about today, both the potential and the current uses of these data. And lastly, and particularly in the last five to ten years we have the emergence of patients themselves understanding that they own the data, understanding that by getting together in communities of activated patients they can use their data for research purposes.

So these patients become the researchers, the governors of the data, and in some way by starting with the patients rather than the clinical data on the patients, we turn the whole discussion on its head and that is a very interesting concept. So I've been strictly coached not to introduce the panelists so you can see their names at the top and I'm just gonna say this first guy here, yeah, is going to present a state of our, state of the art example from Vanderbilt and the ten center national emerged network to tell us about using big data including genetic data for research and to sketch a path forward. And he'll be followed by the second gentleman who is going to review the real risks to confidentiality that concern the VA as it built and used a huge data resource, again, including genetic information for research within the Veterans' population and for what we can learn from that. The lady beyond the second gentleman will cover the various regulations that apply to using and sharing clinical data especially when obtaining individual patient consent is simply not feasible.

And I hope also, and I think, on how institutions are working within these regulations to realize the potential 'cause we've already heard today that many people, many organizations, many partnerships among organizations have overcome these limitations and these restrictions and within that framework so that's what we'll talk about today. And lastly, the gentleman at the far end will tell us what it looks like when we start from the other end, when we start from the activated, motivated patient rather than clinical data as is done in the prototypical online activated patient community, patients like me. What are the data security, confidentiality, and informed consent concerns in these kinds of data networks? So I will turn it over to the first gentleman.

Bill Stead: Window number one. So let me start describing the state of the art by showing how we've assembled a discovery pattern and then I'll give you an example of how we've used that pattern in an Insilco discovery. So what we have done is to extract data from electronic health records and data of all types for example even including messaging between the patients and their providers. And we've created a computed avatar if you will. It's more than de-identified it's almost an assimilation of that patients record that allows us to use it as a discovery vehicle.

> And the simulation is refreshed regularly so you have a longitudinal view. We've currently got about 2.2 million with 1.4 of which have adequate clinical data. We've then sat beside that, if the patient does not opt out during the clinic registration process, DNA we extract from what would otherwise be discarded blood in a bio-bank that is also de-identified. Currently has a little over 150,000 adult records. It took us a lot longer to figure out how to do pediatrics so about 20,000 pediatrics. Adding about 300 per week. Those are linked through a one way hash to provide the discovery platform.

We then use natural language processing algorithms, puristic algorithms to analyze billing codes, all the clinical documentation that is in the record, medication records of all sources and laboratory and test results to come up with an algorithm to calculate the probability the particular patient is either a true case of whatever phonotype or diagnosis we're trying to find or a control for that case. We then have two physicians do chart reviews for a random set of 100 patients and to access the positive predictive value and reiterate until the positive predictive value is over 95 percent. In most cases up in the 97-98 percent range. We then deploy that algorithm with bio view to replicate previous genetic associations to make sure that we're actually able to recognize the right patterns. Then we distribute it at pseudo code. Just logic that a human can recognize and then reprogram into whatever their local EHR is across the now 10 sites in the electronic medical records in genomics network, the EMZRG network and go through another iteration about positive predictive value across sites and then we're in a situation where we can aggregate genetic data across sites.

So this is an example of how we've used that. We started by identifying individuals who had normal hearts. So we wanted to find people who had a normal EKG, no evidence of cardiac disease, no evidence of being on a drug that would affect their heart rhythm or electrolyte changes that would effect it for either any time before that electrocardiogram or up to a month afterwards. We found a little over 5,000 patients across the first five emerged sites. We then wanted to find genetic variations associated with QRS duration and people with normal hearts. So we're actually looking for genetic variance that associate with QRS as a continuous variable within the normal range. We then did a genome wide association study in silica on those 5,000 patients with their data from across sites and that's a study where each dot represents a single nucleotide mutation and the laid out across an X axis of where it is on the chromosome map. With the Y axis showing the strength of the association and we identified several previously known variants that occurred two low sigh on chromosome three. Then we did something you could not do without electronic health records. We in essence identified all of the phenotypes associated with one of those snips. So it's the inverse if you will of a genome wide association scan and we used the 13,000 plus patients that are the super set of the 5,000 that had normal hearts. These included the other 8,000 plus who hit one of our exclusion criteria. So look at that 13,000 in construct to the phenome-wide association scan.

As you can see here across the bottom in this case, you've got where the data lands on the continuum of ICD codes, each dot in this case is a patient instead of a mutation and the Y axis which is the association calculation is based on the association of the variant 2QRS as a

continuous variable within the normal range. And the strongest association was with cardiac arrhythmia's in atrial fibrillation. So then what we did was a to back up. So now that we have an electronic health record we can now take that group that was normal and we can look at what happens downstream. And we therefore were able to construct an Insilco experiment where we looked at Atrial fibrillation free survival on the Y axis. Over time since they had the original normal EKG. And showed that there was a statistical association as to whether you had one G at that allele or a second. This was done in without cost of any significant amount and in hours to days not years. So that's what's possible. Now with that is an example of what's possible. Let's think about the path forward to where we can actually do whole person, if you will, personalized individual and population health. That's really what our goal is. And you've got to do that we've got to have two coordinated work streams one at the intersection of health science and social science research. And the other at the intersection of computation and informatics. And this depicts the first of those, you first got to develop validated instruments for things that we think may be important to personalized medicine that we currently don't know how to measure such is the work at Vanderbilt that Barbara Murphy's done around patient reported quality of life measures on a multi component scale. You then use that measure in a research study of some sort, collect data, analyze it and you come out with our sort of scientific results of what's the strength of association to health, what are the required data elements to track it and what action do you take on a positive screen.

The second work stream is in the computational space and here what we're really trying to do is different from what we're used to doing in most health services or biomedical research. We're actually trying to identify and anneal multiple weak signals that are not statically significant by themselves. Each being derived from a different data source but anneal them in a way that gives us a robust statistical classifier that if you will could be the signature for a fine grained sub population. And to do that you've got a set of things we have to do that are ongoing active work. The kind of work that we have Brad Maylin doing about how you can actually introduce selective mis-information in one of our avatars to statistically keep the re-identification risk low while allowing us to preserve the things that are important to a particular query then how do you do computation across diverse record sources such as the work Tom Lasko is doing around deep machine learning. Think the analog, how DOD recognizes tanks in a satellite picture. And then this sort of heuristic and non-hedonistic algorithm development that I've described in the previous example and the pattern recognition capabilities of the FEWAS. And what best stream of research does is give us hypothesis, you know feature extraction algorithms and phenotype signatures. Now let's put that together. Let's create a discovery platform which has in it the curated data sets which provide us a goal standard to help inform our algorithm development as we look across data sources. As we recognize the features that we need to extract. Determinant signatures, determinate specific decision support, less extract and export that as executable knowledge. If you will the kind of pseudo code I described is the simplest way to do that. You can imagine much more complex ways of doing it. Then those can be incorporated in everybody's electronic health record systems or life management applications as they are used the data flows back into the discovery platform creating a positive cycle as the algorithms get better and as the executable knowledge is refined. Thank you.

Joel Kupersmith: Thank you, thank you very much and what I am going to talk about primarily is the issue of privacy and I am the identified speaker number two *[laughter]* and what I'm going to show you is how to re-identify all the speakers and perhaps release some embarrassing information. Now I am going to use as an exemplar our Genomic data base the million veteran program and genomics exemplifies privacy issues for all data bases but its more intense. It is the hard wiring of our existence and for the most part it does not change for our lifetime. So once it's out, it's out and it's important because not only is it more intense but it will form part of clinical databases at some point in the future and the question that we ask about this is the same question we ask about privacy in everything. And you can't read a newspaper without seeing an article, often on the front page about privacy. We consider this in these government NSA databases. What is the benefit in terms of prevention of terrorism versus the risk of loss of privacy or in terms of catching drug dealers which it's used for also apparently. Commercial databases, what is the benefit when you sign Amazon or you go on Google, there is a little bit of loss of privacy with all that and Facebook, what is the benefit versus the risk or loss of privacy.

Now for genomics, here some benefits and here's some risks. We can predict diseases, valuable biomarkers, prevention of disease, tailoring or treatments, pharmacogenomics, and what will be the most important is we are going to change how we think about disease. We have been using a 19th Century model of organ pathology and that's going to change in the future. It's already changed in cancer to genomics proteomics biochemical basis of disease. And that's a huge shift in the basis of how we do research and how we take care of patients. The risks, stigmatization of the individual and in this case the family as well, especially first degree relatives. Denial of life insurance, GINA law which is the Genetic Information Nondiscrimination Act covers health insurance and employment. It does not cover life insurance or disability. Inappropriate marketing that's used by individuals and of course various other things.

Now one of the reasons we are so concerned about privacy is because of the benefits of data sharing. We want the data of all these databases that we've discussed in the past two days to be available to the world's leading experts to put it to the best possible use. If we put patients to any risk whether it's loss of privacy or any other risk we want the information from that to have the best possible use so we get the best science from it. The other point is that no matter how big the data, and we are building the Million Veteran program which is going to have a million veterans in it, it's still not going to be big enough to study some things. So we have to share these databases. And that also may entail a risk to loss in privacy. Now when we started the million veteran program there was some resistance to do it for a variety of reasons and various stakeholders both within government and out. So the first thing we did was a survey of veterans and this showed that 83 percent of veterans felt this should be done. That we should collect this information and create a bio bank and database. And there were some various reasons as to why they would or would not sign up but they wanted to receive information about their health. They also wanted to receive the information about the studies which is important. When you

create these databases it's important you realize that people join because they would like to know what's found. But they all had serious concerns about privacy. See most of these they are all privacy issues. Most 95 percent and above had concerns and serious concerns. On the other hand and I think this is a very interesting finding. On the other hand they wanted to share the data and there's a hierarchical nature of that. 8 percent wanted to share it with academic medical centers. 70 percent with other health related government agencies and still a majority with industry.

And I think this shows that often we think that the public doesn't understand these things. Doesn't really want in and we have to explain it but this shows that they do understand. These veterans understood what the nature of the data was and what the benefits of sharing it was and to whom or with whom it should be shared. So 83 percent thought that the program should be done. They felt that it helped veterans. They were willing to have the data shared with academia and government industry, strong concerns about privacy and wish for sanctions for those that violate trust.

Now this was done by an outside group actually from John Hopkins. Not by the VA itself. The same group did a National survey outside the VA and the results were quite similar, the numbers were different but also interesting, the sharing, 92 percent thought this it should be shared in academia and 75 percent with industry. So even higher numbers for sharing. And here's another important point about privacy, that it is as you see from this survey. You can see from this survey it is crucial in maintain public trust. This is a quote from the presidential commission for the study of bioethical issues. Which took on the issue of whole genomic sequencing. And this is both from their report and from their press release. "Without privacy assurance in place individuals are less likely to voluntarily supply the data, et cetera, et cetera, so public trust is a huge issue, if you lose public trust much of what we're talking about is going to be very difficult to do and as you know physicians, academic institutions, at least relative to others have high public trust and we don't want to do anything that alters that. Now when we started the million veteran program, we did a survey as I showed you but we also worked with veterans groups and veterans themselves and we did a number of other things to establish trust with veterans including absolute and complete transparency and considering strongly their input on any issue.

All right, now re-identification is the danger to privacy. We have always had very different polices for de-identified and identified databases but as found several years ago, re-identification of the de-identified data bases is possible. In 1997 governor William Weld put out a large database of public employees health records, hospitalization records and so forth and within three to four days I think it was, he was identified within that database. And actually published in January of 2013, almost 50 they said, individuals were identified through a somewhat complex process but it only took three to seven hours in a supposedly anonymized genetics database. Now I'm not going to go through all the details and I wanted to just get something from the literature that was actually done to show you how this is done. On the left, is a health database which actually also included genomic information and this is a so called candidate database. On the right is a reference database. Now this is a voter list, a voter

registration list. Which was bought. You can buy it. You want to run for office you want to do this you can buy a voter registration list. There are many databases like this public and also quazi-public databases available. And as you see there's an OVA .This is not a HIPPA secured database and there's no promise of privacy actually made with this database but you can see that there's an overlap in three items of information. And out of that you can identify a certain names of a certain number of individuals and if you can't you just plug in another database and you can then identify even more until you get down to almost every one. And that's how it's done in general.

Okay. I'm going to skip this because Dr. Thorpe is going to go into that much more detail but I want to just talk about how we approach these things from three points of view. Policies that databases technology and laws and regulations. Now on these databases we need, governance is very important and we need strong governance. We need clear functions of leadership, access control management, security management and so forth. If not all different people at least in functionality we need oversight boards again in functionality to look at science, privacy and ethics. Unless science and peer review I believe is extremely important use for research databases unless they are used for the highest possible science. You shouldn't again put people to any risk for identified or limited datasets which are partially identified you need good data use agreements and that's extremely important. And transparency. Transparency of policies, procedures and of the risk to loss of privacy. So the question comes up, In view of the possibility of re-identification, should policies be marketed different as they are now on so called de-identified and "identified" data.

Now I don't think we should panic about this and I think that there are some things to consider. In general, de-identification when we think of large databases, we think of as off as as many examples have been given. Maybe large, maybe Medicaid administrative data type data bases where there's no possibility of re-identification. There are hundreds of thousands of individuals in them and millions and we don't consent for use of those. We don't get consent. We could possibly use them anyway if we try to get consent on all those people. So we don't think the consent should be done. So there's a number of questions that arise. First of all transparency. What do we mean by transparency when we tell individuals about these databases. Do we say you're completely safe from re-identification, or your mostly safe, some people have said that this should be put on a continuum and not absolute. But if it is on a continuum we don't know how to quantify it. We really don't know what the proportion of risk is. And secondly the issue of consent versus transparency. Are we just transparent about it, which sometimes we're not now and we should be. Or should we get some sort of consent on people. And these are questions and you know I've been in many discussions here in Washington and the IOM and other places on these issues now that these large databases, genomic and otherwise are coming to the floor.

Now there are some technology solutions to this and one is the distributed database and yesterday Jane Woodcock mentioned in a phase four study how this was used. You have a number of databases behind their own firewalls and you just pull out as kind of as a need to know basis. You pull out the data you need for a particular study and I think this works it

seems. And many people are using this in a variety of databases. And then there are other computational access and so forth, disclosure filters here, you can have patient preferences. Actually you can put in something that the patient decides not to be in certain types of studies. And then finally laws and regulations. What are the appropriate sanctions for misuse of data. We have monetary sanctions for HIPPA violations. We have criminal sanctions for identity theft and that sort of thing and we have litigation possibilities. But we're chasing one person around the world now who has released a large amount of data and if you ask five random people what we should do with him if he ever came back, you'd get five different answers. So we're not sure about all these things. I'll sort of skip certificates of confidentiality. HIPPA safe harbor provisions, 18 of them. We need to evaluate that. We need to evaluate what are the appropriate safe harbor standards and we're actually the VA is doing some research on it. Should there be a re-extension of the GINO law is another question. I think there should and how should first degree relatives be protected and this is probably going to come out more in the plaintiffs' bar in litigation more than in laws I think but we'll see.

All right conclusion, we need to ensure the best possible scientific use of information and specimens that individuals vary and volunteer including sharing. We also need to make sure that privacy and security of data. If we lived in a perfect world, we could do both perfectly. But we don't live in a perfect world. So we have to somehow find that sweet spot and find the policies and laws and regulations that surround that sweet spot so that we can function to use these databases to their highest ability and assure the most privacy you can. Thank you.

Jane Hyatt Thorpe: Thank you very much Joel that's wonderful. And now we'll here from Jane and even more on the regulations that we will work within or try to change, or both.

Wonderful and Thank you and Welcome. I'm thrilled to be here again. These are always wonderful conferences so thank you my fellow panelists and to the institute and all of the folks who helped put this together. I get to be here today showing my legal stripes which will probably make me easily identifiable in any database because I will always be the one carrying the flag for the laws and regulations. But I do think that they serve a purpose particularly as we're thinking about very sensitive issues related to privacy and security. However, I am not here to tell you that the law and regulations are barriers to the contrary I actually, my approach has always been that the laws and regulations create opportunities and we need to figure out how do we think about our current legal and regulatory framework, think about the intended uses and goals of our activities and then try to figure out how we can marry these together in a way that ensures privacy and security but also generates the very valuable results that obviously research using very large data bases and other exercises using very large databases can create.

So before I jump in too much further. I will give you a slight overview of laws and regulations but I promise you this will not be a legal lecture by any stretch of the imagination. I will not ask you to go through that with me but I'm just going to mention several laws that I think are probably the most key and critical to the discussion. It's not an exhaustive list. For example you'll see some laws aren't referenced here. I understand FERPA related to education records was mentioned yesterday which also is very relevant particularly when you thinking about students medical records and where they may be held. Dr. Kupersmith mentioned GINA the Genetic Information on Discrimination Act. So again the examples that I'm going to give are meant to be examples but I think they are some of the core examples that should govern are thinking about privacy and security and the use of data both at the individual level as well as the population level. And of course when you're thinking about large data sets.

Towards the end I will talk about two common themes that you'll see. I'll highlight actually as we go through the laws. One is the role that research plays and across all the laws and regulations that I will highlight there are extensive opportunities for valid credible research to be done and for disclosure of information to be made that support those efforts. The other common theme that I will touch on at the end as well but I would ask you to watch for it as we walk through these laws and regulations is the concept of patient consent or patient authorization. And the role that the patient really does play because at the end of the day you don't get to a large data set of information without starting at the individual level and collecting that information at the individual level even if it's the identified. And then I'll conclude with some thoughts on thinking about the framework going forward.

So the first law I'd like to mention is HIPPA. I know we've talked, there's always been a lot of discussion about HIPPA. It's been an evolving framework of course this year HIPPA has gotten a lot of attention because of the new changes in the regulations stipulated by Hitech. So it's actually been a very big and very exciting year for HIPPA. Some of those changes I think have been positive and were intended to align the HIPPA rules with other rules such as the common rule. Others I think are more difficult and we're trying to figure out exactly what they may mean and what their implications are. But in some the privacy rule actually sets a federal floor for disclosures and use of patient health information. It also establishes individual rights which I also think is a critical piece of this discussion. The interesting thing about HIPPA is that it really only applies to three broad categories of stakeholders. And so when you're thinking about privacy and security everybody automatically thinks about HIPPA or most of us think about HIPPA as sort of a knee jerk reaction but actually one of the things we have to consider is that HIPPA only applies to activities by covered entities. So health plans, providers and clearing houses. As well as organizations who may be working on their behalf. And this definition has actually been expanded to include health data organizations. But there are a lot of activities that actually occur outside the HIPPA framework that aren't being conducted by health plans or providers or clearing houses and we sort of have to think about moving forward, what is the intersection, where HIPPA stops and activities may be occurring outside of HIPPA regulatory framework are there things that we need to think about and make sure that patients in particular are aware particularly thinking about research. And of course HIPPA applies to only individually identifiable information that is held in any format. So information that is electronic or paper or oral that information is protected.

In terms of disclosures, actually before I get to that I am going to talk about the individual rights really quickly because I think when we think about population health we really have to start with the individual. And so a couple things in particular I'd like to point out related to the individual rights is the right of access. Under HIPPA individuals have the right to access and view their own protected health information and now under the HIPPA mods they also can ask for that information in electronic format. So if they come in and they would like it to be put on a USB stick they have that right to access their information. They also have the right to amend their information. So if they feel like the information that's being held in a record about them is incorrect. They have the right to request an amendment of that information. And I think that's also particularly critical as we're think about collecting information that's valid and credible and useable. Giving patients that opportunity to actually correct information that may be held in any records about them and then how that might implicate the sharing of information downstream from there whether it's for treatment purposes payment purposes or research purposes or ultimately use in a large data base.

As I mentioned HIPPA is very much a permissive law. There are a number of disclosures that are authorized without patient authorization. So I just have this slide to point out that there are a number of uses of data that are permissible without patient authorization and a lot of instances particularly when you're thinking about research or research on a large population. Often times what I heard particularly when I was at CMS is that it's very difficult to get authorization from every patient that you would want to include in a data base or every patient that you would want to include in a research project. And so I always went back and sort of thought well okay are there other ways under HIPPA that this information can be disclosed without patient authorization. There are two keys ways that I'd like to highlight. One is that it's a limited data set. Which does still include identifying information and you do need to enter into a data use agreement but limited data sets have actually been very useful for research and other purposes because they do still include some key identifiers, including city, zip and other dates of service and things like that. And of course the other element that Dr. Kupersmith spoke about is the concept of De-identified data. Once data has been de-identified and those 18 identifiers have been removed that data is no longer protected by HIPPA and can be used for any number of purposes or uses without any HIPPA regulation what so ever. However I think as Dr. Kupersmith also pointed out one of the things that we do need to think about and I'll highlight this in my conclusion is what does de-identification really mean. And I became acutely aware of this when I was working on a project to develop public use files that were based on Medicare claims data and as you can imagine CMS takes very seriously it's duty to ensure its privacy and security of Medicare claims data. And I was amazed at the level of the technical level and the rounds that we had to go through to ensure that those data bases were actually considered de-identified just goes to the points that have been made by earlier colleagues. We really need to sort of reconsider what does de-identified mean and is there really such thing as de-identified now that we have so many different sources of information that can be married together in literally an instant and used to identify individuals. But for the time being we still do have the HIPPA safe harbor for the use and disclosure for the de-identified information and HIPPA doesn't apply to those disclosures. And of course there are disclosure for patient authorization.

Touching a little bit on the research for in terms of HIPPA that no patient authorization is required to release patient protected information to public health authorities that may be conducting research or other public health activities. So that's a very broad permission under HIPPA. And there are also permissions to disclosure protected health information for research purposes. Sometimes the research will require patient authorization but in other instances you can either work with an IRB and to get a waiver or an alteration of that authorization requirement. And ultimately actually now under the new rules there are opportunities for compound authorizations as well as authorizations for future roofs. Which is really actually been highlighted as a challenge in the research field because when you're engaging with a patient and you're explaining to them what it is that you intend to do in terms of your research or researchers working with patient or patient population it had to be for a very narrow specific use, that research purpose. But now under the new rules we're allowed to combine authorizations as well as think about future uses as well which will make it easier to interface with a patient and get those authorizations for future activities. However, as I said I'll come back to this in terms of what do we really mean by patient consent or patient authorization and how is that evolving in the concept of big data.

The common rule, very quickly on the common rule what I just want to point out is the common rule regulates human subject research. And so all research that's done that involves an individual person. So physically an individual person or an individual persons information. That's considered human subjects research. And in order to conduct human subject research you have to have patient consent. And that has been a critical theme of the common rule since its inception but as I said now trying to marry up HIPPA requirements with common rule requirements, that's why the concept of compound authorizations and future use has become so critical because there's been an effort to further align HIPPA with that common rule around that concept of patient consent.

Moving on to more sensitive information there are a variety of laws at the federal level and the state level that actually protect more sensitive information. And so 42CFR Part 2 also called Part 2, is an example of that. Protecting information about a patient that includes substance abuse records. Ad this is defined very broadly so any provider that's participating in Medicare, any provider with a DEA number is considered to be a provider of substance abuse services and those patient records that include substance abuse information are protected. However, back to my two common themes substance abuse information may be released for research so it does have that exception and substance abuse information may also be released with patient consent. So again back to those two common themes. Release for research and release with patient consent.

Also at the state level there's a lot of activity and actually increasing activity at the state level but in particular related to some sensitive areas of health information there are a variety of state laws that protect HIV and AIDS information, mental health information and of course information about minors. But again a common theme through a lot of these state laws is the concept of allowing release for research and also allowing release with patient consent. And actually there's been a lot of activity this year on the HIPPA front but I think we're going to see more and

more activity at the state level. Not just related to sensitive types of health data but actually related to a much broader set of data. There was an interesting article in the New York Times a couple weeks ago about thinking about not just health information but also other personal information because as folks are going in and pulling the information from different sources and mining it to kind of figure out what our preferences are, what our patterns are, states are increasingly looking into whether or not their own privacy and confidently laws need to be strengthened. And while I think the initial focus of this will be more on personal information about preferences and the like, health information will certainly be captured, I think in that discussion. So there will probably be a lot of activity as we look forward to that.

Just a couple other federal laws very quickly. Privacy Act of 1974 again release of information that's held by the Federal government can be released with patient consent so back to that theme and then of course the freedom of information act allows any person to request information from the government that they feel like would shed light on their activities but there is an exemption that does protect personal information. Again sort of balancing that public interest versus privacy interests.

So we clearly have entered this era of big data, of big information. I think it's probably here to stay and so we have to sort of think about how do these laws and regulations, and again this is just a very small snapshot of these laws and regulations but how do we marry up the legal framework with the current expanded uses of data, the research that at first are underway and frankly just the sheer volume of information that is available now. I mean even five plus years ago we didn't have immediate access to the sheer volume of information that we have now. And so we have to think about whether or not the current legal structure actually still works in this new era of big data and volume of data. Not only from the perspective of individual patient privacy but also from the perspective of the common good and the public interest. Especially when you're thinking about population based research and improvement in public health and populations health. But I would say for the time being given our current legal framework we come back to those two themes that I mentioned earlier which is each of these legal frameworks there are opportunities to release the information without patient authorization for research. So under HIPPA, under the common rule, under the state laws that I mentioned there is that common theme running throughout all of those laws and regulations that does allow release of information for research. And I think actually it's already been stated, we do need to think about the role of research because there's a huge opportunity that's acceptable and permitted under the legal framework to use patient information through research. And I think as we think about, it's a comment I actually made as we're thinking about the growth and development and the use of registries, figuring out what is the end goal. What is the ultimate use of the information and what are we trying to do and then trying to figure out how does that marry up with the laws and regulations and I think we can tailor the use of big data to fit within the current legal framework and where that we may need to do some tinkering obviously is a discussion for the future but there is an existing framework.

The other element, I said common denominator is patient authorization and consent. I think as we talk more and more about a patient centered approach to healthcare and healthcare

improvement this is going to play an increasingly important role again all the laws I mentioned allow for release with patient consent but moving forward I think we're going to have to do more thinking about what does that really mean, what does that mean to the patient and do they really understand the type of release of information that they're authorizing. So I'd just like to conclude with a few thoughts moving forward things that I think from a legal perspective we need to think more about. The first actually would be a framework for patient consent because while it is a common theme throughout all those laws and regulations the requirements for patient consent or patient authorization are different in each. And so you may be doing work or research. That actually crosses across several of these laws and yet you may need to have different consent forms or different authorizations for each one of them. So I think we need to take a more holistic approach to what is patient consent mean, how is it conducted, what do the forms or explanation, what's included but requirements need to be met and think about a more consent uniform approach. More holistic approach to patient, patient consent. The second element I think we need to think about more clearly is the concept of di-identification. I'm not sure we have such a thing as de-identification anymore just based on my personal experience with those public use files. It was incredible to me the quickness with which individuals could be identified from what were considered de-identified databases. And so we may need to reconsider whether the concept of de-identified and the benefits that come with de-identified which means that HIPPA no longer applies, does that still work in this framework of big data.

The third thing I think we need to think about is similar to patient consent a more comprehensive or holistic approach or system approach to our laws and regulations. Right now they're very siloed. They apply to particular actors or particular actions but I think we need to take a broader approach and recognize that we're not just talking about health information anymore. We're talking about linking it with other information and again possibly identifying individuals. And finally the other element I think we need to rethink is the concept of sensitive data and what does that mean. Interestingly as I've been working with some states on registries and their health information exchanges, certain populations have been excluded. So individuals with HIV/AIDS, mental health, those records have been excluded and what we have been adhering anecdotally from some of those populations and some of those individuals is that they would like their information to be included in these efforts so that they have the benefit of the information that is ultimately generated from these efforts. And so we may need to think about how that is interpreted as well. So very quickly just a quick plug for the work that we are doing. We have a wonderful online resource, healthinfolaw.org, so if you are interested in these laws and regulations and how they apply we would love for you to visit us online. You can also follow us on Twitter. But our goal here is to really break down perceived barriers from these laws and regulations and also help think about where the opportunities exist as we move forward. So thank you.

Ben Heywood: Hello and thank you guys for having me. I'm going to try and go quick here, keep on catch us up a little bit on time here. So hold on. So what I'd like to talk about today, first of all talk a little bit about Patients Like Me and a couple people have mentioned what we do. Then talk a little bit about the open research exchange which is a new project that we're doing that's funded by the

> Robert Wood Johnson Foundation that I'm very excited about and then move that into some of the transparency and privacy things that this panel has discussed. And then lastly just talk a little bit about some of the opportunities and challenges we have as we think about connecting "our big data" with your "big data" that we've been talking about over the last couple of days.

So on one level Patients Like Me what I guess thinking about this, real world big data. It's not the controlled clinical data that we've been talking about over the last day and a half but we actually since 2004 have been taking data directly to patients in trying to understand how it effects their care and it actually improves their outcomes. And just to give you a sense of what 2004 was. Facebook was still called The Facebook. A human genome was $750,000 now less than $1,000 and the hi-tech vac was five years away. So think about that start. So we've basically been studying the use of real world data with patients over those eight years.

So what is it? If you don't know it's a website for patients. It's a community of patients, mostly with chronic illnesses coming together, tracking in a quantified way, treatments, symptoms and outcomes in a way that they can share amongst themselves, learn from each other, track their own health and engage in their own health through that tracking and then obviously learn from the real world experiences of others. But we really in those eight years a lot of time was thinking about the measurement of health at the patient level and what's missing. And what we've seen over the last day and a half is a tremendous progress around data standards and interoperability and those are big challenges that are very important and we're making big progress on but when we looked at those were challenges we couldn't take on back when we started and we started to look at other challenges I think we're going to discover soon which is when we connect all these systems together we actually don't know how to measure health effectively with many, many chronic illnesses and that the data in the system won't actually help us solve many of the problems and so, just real quick, as I've mentioned what people do on the site within the community, we talked a little bit about this.

Who our members are so we are a network now of close to $250,000 patients. PCORI gave a nice name to what we do I think which is, "Patient powered research network". We are clinical research on the backend. We primarily work with pharmaceutical companies and academics to mine the data and prospectively survey our patients. These are sort of the personas of the patients that we attract on the site tweeter tracker, activated patient base, leader connectors, research advocates. There are some personas that aren't attracted to our site. Those who are actually a lot more compliant with the system who actually engage in the system and actually take direction much better from the system. Those typically are not ones. We tend to service people who are seeking support or answers or evidence that they aren't getting from the system today.

So just to give you a sense of scale of data. This is from a recent insomnia study we did. We have close to a quarter a million members, data points, 63,000 of these patients with chronic

illnesses have reported some insomnia. Over 184,000 reports there. 70 percent of those with moderate and severe insomnia and then just also patients that were just talking about insomnia. So 83,000 sort of spontaneous discussions around insomnia. But also going to what someone spoke about yesterday, our ability to drive deep, we did a perspective survey in the context to this, but we actually reached out a 90 question sleep survey to 6,000 members and we were able to get responses in two weeks. So we did a little PR on this, we're actually doing the work to publish this over the next little bit here.

So what can come out of what we've done. Just I'm going to touch on some really quick research. Really deep disease modeling we have an amazing ALS disease model that is incredibly predictive within a month. If you give us two data points we can tell within a month whether you're going to either prevent or pass away from the diseases. That was used to do a real world comparative effectiveness study of lithium and ALS published in Nature Biotech in 2008. Just some great data around Parkinson's just showing the week over week variability of the disease is higher than previously thought and was assumed in trial design and then some great data on MS, some of our deepest diseases But just to get to some of the other literature we talked. I mean I think one of the things about sharing data that we've shown is it can actually improve outcomes in very meaningful ways with patients directly so looking at HIV patients who this is a user survey that we published in the *Journal of Medical Internet Research* to show that HIV patients strongly agree that they took more interest in their lab values because of the system, understood the consequences of drug holiday and then actually overall across all of the diseases about 12 percent of our members change their physician because of what they learned on the site.

Just a small research team but these are our publications over the last – peer review publications over the last six years and that's important. We've done a lot of peer review work to actually establish the legitimacy of us as an evidence platform and here's a great study that we did in conjunction with the AAN releasing new guidelines for the care of epilepsy we actually surveyed our epilepsy population to see how well they were meeting those standards in the clinic and you can see very large variation across. PCP neurology and epileptologist What I love about this is one just in the concurrent nature actually as those guidelines were being published we actually had patient reporting data about how they were being, about how they we actuating in the real world but also talking about low hanging fruit. You know we have a member, a patient with epilepsy who came on our site and all that she learned on our site was that an epileptologist existed. I'm not talking deep research, it's just that they existed and she went to an epileptologist, got a better care, got a treatment that really fundamentally changed her life. And again there's lots of low hanging fruit when you go directly to the patient and you give them the tools to understand the information.

So this is an eye chart but I actually put this up here to just talk about how we systematically and really scientifically and comprehensively are approaching this problem. So this is how we map out the patient caregiver journey from hundreds and hundreds of ethnographic interviews that we've done with our population as well as what we've learned from them using the site. And it just starts to breakdown very systemically what the various stages of the journey of

chronic disease are, how patient events, the events that are occurring, the feelings they're having, the questions they have and when they hit depending on the various diseases they're having. And I only put this up here because you can begin to break this problem down and begin to measure and understand each one of these pieces in a way that can be systematically approached with the right data and the right studying.

So this got touched upon earlier, this is a very exciting project that we're doing this year that we're doing with funding from Barbara Johnson Foundation. One of the things we now have on the system patients with over 2000 different conditions. We probably only measure about 40 of those well. 10 of them exceptionally well and about 1960 of them don't have a good patient reported outcome. And so we wanted to design a system that would allow expert patients, clinicians and patient report outcome experts to come together in an open environment and rapidly create and validate PRO's for diseases that we care about. And so we've actually in Alpha, in this platform we have about five pilot researchers using it to build PRO's right now. One of the things we're baking into the system is a different way. I think somebody talked about PRO's New York. The New York Public Health commissioners talked about PRO's are not typically PRO's, they are experts views of what a PRO should be and what we're trying to do is actually make PRO's a actionable engagement tool for patients and to do that you need to be clear, the information you need to answer. Well that's true of any good PRO, efficient, respects the time of the patient but relevant. Like actually has to relate to the patients. Educational. There's opportunity while engaging them and asking them questions what's in and out of their condition and what they should care about. And we actually we've talked about this it's harmless but we actually want them to be positively activating. Our joke internally with our science team is that depression scales are pretty depressing to take. And they don't need to be. They can be activating and positive in framework. And then actionable obviously making it so they can actually make a change. Improve my dialogue with my provider about what I should be doing.

So going to the privacy thing in the last couple of minutes here we actually have next to our privacy policy which actually I am probably one of the few people in the world who reads all those HIPPA brochures in the doctor's office but our privacy policy is pretty similar to what those HIPPA brochures say about what we can and cannot do with your data but we also have what's called an openness philosophy and I think this relates to this idea of sharing data and the importance of it. And why that's important is, one two of our core values as a company around openness and transparency, so and how do we live that. So transparency, you know we're a for profit company. Patients often ask do we sell our information and we're very explicit about that. We're also very explicit about the risks of being re-identified and I think that's important from what our panelists talked about earlier because I'm actually not one to bring the boogey man of privacy into the conversation. I think this data should flow freely obviously our business model has become a bit dependent on it but the reality is, is that there really is no such things as a de-identified data set. All data sets will be re-identifiable and so the thing I care about is when I contract with a company or a researcher, I care about them certifying that they won't re-identify contractually and having penalties associated with not doing it because I think that's going to stop people more. I think the other thing is we talked about GINA. I think it's very important we look at extending that to the medical information non-discrimination act and an equivalent of that

as well as extending the protections of the GINA because again this is going to happen to everyone at some point in time and so this is a story from 2008 about us. We had Nielson, a company scrapping our website for data that they were taking without permission. So we let all 70,000 users know, "Hey this is what we do. We reminded them about selling the data but reminded them that other people can come in and see their data." That was a big deal at the time and hit the journal. And you need to understand the article itself is not important but I think you need to think about your relationship with your users, your patients in the context of transparency and privacy and do you have a relationship that can actually sustain this kind of scrutiny. So challenges to be resolved.

So I think look, we continue to want to create, make this our big data with our patients meaningful in the context of regulators and decision makers. So FDA and NICE. We actually published an article in Prosper. A framework for patient reported outcomes, safety measures in the journal of drug safety recently in working with the EMA. You know every time we start a new we get different enthusiasms for this methodology so that's a challenge and people all, I think the big question and a number of you even in the audience always want to understand the validity of patient reported outcomes and what does that mean and so some of the things about verifying and EMR integration will actually start to improve that and validate that the data we have is meaningful and potentially more valuable than some of the clinical data. And then obviously devices and sensors are a big part of where we're going to be going and I think everyone here will be thinking about going. And again I think big data for us needs to start and end with a patient because it's there data and they're the ones that can avoid all of the HIPPA and all of the privacy issues. There the ones that can manage what they do with it and as we've heard today. They want that data to be shared and used to actually improve care. So lastly just to end I think there's real opportunity to going directly to patients. We have a percentile curve on our side for ALS patients to allow them to know exactly how they're doing. Integrating with other data sets so we every night download clinical trials.gov and tell every patient in our system about every trial they're eligible for. You know really again engaging patients in this you get something, you give something. It's a mantra on our side about how you actually engage patients around data. So again the new open research exchange is just a great opportunity for doing patient reported outcomes in a different way and I think we'll hopefully explode the opportunity to utilize them in both our systems but also in clinical practice but lastly just again. This is a way to engage patients to be patient centric outside the home where most of the living and the health happens and engaging patients in their own data is a real opportunity to actually make the system better. So thank you.

Joe V Selby: Well I want to thank all four panelists. I was a little bit anxious about sharing this particular panel I thought it might be depressing. But in fact Jeff you were right. It's just a great way to wrap up, ask come to the microphone right away and just put one question to the panels. Most of these big data applications that we've been hearing about do involve sharing of data across systems. Most of them go outside covered entities. Most of them are not going to be able to get individual patient authorization. Most of them are allowed as all of these demonstrations prove under the HIPPA regulations and others but my sense is that a lot

of systems are reluctant despite HIPPA protections and my sense is that we need to find ways to talk to the patients within these systems. These patients whose data are used. And I just wander based on your experience any of the four of you have a perspective on what do healthcare systems that are beginning to link and share data, disclosure data for research purposes or for clinical purposes say to their members in the process so that to pull them really pull them more into the process to make them more like the patients with insomnia who go online and are really active and interested in research.

Joel Kupersmith: I'll start anyway. First of all speaking about organizations that want to be behind the firewall, government and the VA want to be behind the firewall, we are behind the firewall and we haven't solved the issue of sharing the data yet I must say although my intent when starting this project several years ago was to do that. I've had this discussion and lawyers frequently disagree with me but there's a couple of ways of doing that. First of all the distributed database is protected pretty much and I think it is a good approach in many situations. Secondly as far as how you interact with a patient. You know we ask for example, academic institutions say ask for permission or tell people that they're going to have trainees see them and medical students and residence and so forth and I don't see why something like that can't be applied here. Where we ask patients we get their permission for this kind of database use. I think we're going to get into trouble. Now the other way to do it is just to say we're going to do complete transparency and we're not going to ask any kind of consent. But I do think it's a good idea to try and interject into that whatever is legally possible.

William W Stead: Let me provide an additional perspective. When we at Vanderbilt started, decided we would like to collect the bio bank we did a community focus group and Tennessee is a reasonably conservative place. And it was clear that in large segments of our community people were actually scared of receiving care in a place that did research. It was that – so we had to actually back up and do a broad based community advertising campaign around the importance of asking questions. And things like why are there nine justices on the supreme court because nine opinions are better than one. And that in over a period of time the focus group showed that we had changed to where people recognized where people wanted to receive care where questions were answered. That was a very basic step one and then the other thing we've done is with any of the communication about what we're doing. We have had the discipline to stop and interview patients, sample patients after they have had a chance to receive the communication to see what they actually took home from it. And to stop and iterate until we got the communication to where they actually understood what we were doing. So it takes great discipline to

communicate well with people with widely different backgrounds, education levels, et cetera.

Ben Heywood: Yeah. I mean look. I think there's a few things that lessons we've even learned in terms of our internal small team. One is just the value of the consumers marketers perspective. I think most of you in this room are researchers and we work with a lot of researchers who hear the term marketing and run screaming out the door in terms of wanting to engage but when we do research studies and our marketers work with the scientists to design outreach and the language we get significantly higher response rates. Not small like almost doubling. So I also work with researchers and clients that don't want to hear that marketers are thinking about science. And so that's just a cultural thing and by the way it's hard because they are a little bit like oil and water even within our organization so you have to learn to trust and understand how that process is because I think that's very important. I think secondly I think it's something we have an advantage. Our facility around this is it's not just about collecting the data it's actually having access to those patients on a longitudinal basis as well because we're going to find things we don't know and wish we did know. And actually I think Brent Jones spoke about that very nicely. And having the ability to drill down is very important. And so we're working with a major health system right now that has millions and millions of people with that preview but they can't survey 5,000 people with this condition because they're not allowed to or it's too much work. And so they're paying us to do it. It's sort of silly and conceit but it's a reality.

Joe V Selby: Okay good. Let's go to the microphones and we will start with you.

Caroline Coughlin: I'm Dr. Caroline Coughlin and I'm also an attorney. I have a question for Ms. Thorpe. Was there any effect from the supreme court decision about the Vermont records? I don't remember the details, frankly I was disgusted with the result where data from pharmacies that was required to be turned over to the state of Vermont the court held that the state of Vermont had to make that information available to a pharmaceutical manufacturer so that the pharmaceutical manufacture could market to the patients and the physicians.

Jane Hyatt Thorpe: Yeah. That was a very interesting discussion. For anyone that's interested it's IMS vs Sorrel and I think it was absolutely precedential and what's interesting I think is the concept of free speech pitted against privacy of health information. And when I made a comment about a lot of

activities occurring outside of the HIPPA regulated world. Pharmaceutical manufactures, device manufactures I think are a perfect example where their activities are not regulated by HIPPA or other laws and regulations and yet they collect massive amounts of information that they turn around and use to identify preferences patterns and reach out to patients as well as to physicians. And I think there's been a lot of valid controversy about whether or not information should or could be used for that and obviously what the court held was that those organizations have a free speech right to use that information to reach out to individuals and to others and I think that's going to be a continuing issues, not just with health information but also when we think about big data in general is where do we draw the line between the public good, the public benefit and this concept of free speech and I think that's going to be highly debated and very challenging sort of line to walk because on the one hand they're sort getting to there are a lot benefits of making information available and identifying themes and trends and patterns to patients and others. On the other hand I think the message that sends is that then there's a hesitancy on the behalf of individuals and patients to actually share their information because they don't understand how it may or may not be used and then they show up as part of a database that's being used to actually market to them directly. So I think there's that sort of, I didn't even touch on sort of the moral element of it but I think that's definitely going to be critical issue going forward.

Caroline Coughlin: Yeah because this was sensitive information and it wasn't being used for the benefits of the patients. It was being used for the benefit of the manufacturer.

Daryl Roberts: Hi, I'm Darryl Roberts and I'm a Senior Policy fellow and Evaluation Researcher working for the American Nurses Association. I had the privilege, several years ago, of writing my first master's thesis on HIPPA and why it would fail and ultimately a lot of those failures have been overcome with this latest iteration of HIPPA but it's been interesting to see the growth of the privacy industry and the de-identification industry. The organizations that you can actually hire to re-identify data for you. Another interesting thing is how little data it really takes to identify someone. Case in point, I had one of my graduate student come up to me about five years ago and he says, "Dr. Roberts you probably shouldn't wear your ID for the conference that your attending outside because I can show you in about five minutes a photograph of your house using just, and he did it, using just the name on your badge and the conference that you're at. It's not that hard to figure out. From there you have an unusual first name, you have a PHD, you're at a conference here, you must be Darryl Roberts." And he showed me a photograph of my house in 10 minutes. I took from that and I said, "Well what if you

didn't have my name? What could you know about me? " He said, "Well with just your zip code the name of the conference your attending and the fact that you're a registered nurse with a doctorate I can identify you by name in another ten minutes." And he commenced to do that. Are we in a period now with the growth of data where culturally we need to reconsider the definition of privacy and what expectations we would have of privacy instead of clamping down and clamping down and clamping down.

Joel Kupersmith: I think that this is a point that's frequently made. And the other point that's frequently made is that young people have a whole different attitude about it than older people. That's not true. In fact in our survey or the survey that was done in the general public related to our initiative and many other surveys have shown on certain issues young people have the same attitudes as older people. Certain issues of privacy. When they're hurt, when they conceive harm by privacy release. I think we had – let me just say a couple things about this. First of all we also had a communication effort as was described for our million veteran program. We work through veteran service organizations and people like that and veterans groups. So that it is important, and I think this is one thing you're saying, to have a communication effort about this. And one of the things that we are most concerned about loss of privacy is stigmatization. As things in our society become less stigmatized we're going to have probably less concern about privacy. We have a big program in the VA to de-stigmatize PTSD and the generals, active duty generals coming out and all that sort of thing to try to publicize that but as you saw from these surveys the expectation for privacy is still very high. And if we just try to say, "Well you shouldn't have that expectation." We're going to get into a lot of trouble.

Ben Heywood: Yeah. And so I mean I look at this in three ways. I think we have to sort of begin to think about privacy itself. The harm from privacy and I don't mean just the loss of privacy being the harm I mean additional harm and then the stigma question that I think you raised. And I think we actually do need to begin to focus on mitigating the harms and that's why I mentioned extending GINA to medical information and to think about stuff and activities like that. But actually the stigma thing is very interesting because you know is this discussion of privacy and this focus on locking down, is there chicken and egg with stigma. Is it stigmatized because we don't talk about it and it's locked down and if we were talking about it and it was more open, is that a virtuous cycle where we can actually begin to eliminate the stigma which again will then reduce the privacy concerns. So I think we really need to look at all of those things. And I will say from a journalism, if there are any journalists in the room, the thing I hate most about anybody writing about any topic in healthcare is that there is a line

in every article that says, “And of course privacy is a concern…” And stop. And they don’t say why, they don’t say the downside of privacy. They don’t actually characterize it in a risk benefit way which we all know it is. And so I think there’s some real work there to do in terms of just how we talk about privacy.

Joe V Selby: And I’m afraid we have time for just one more question. This is a fascinating panel and your questions are great so we’ll take on last one.

Gerald Shots: I’ll make it very quick to professor Thorpe. I’m Gerald Shots from Pellegrino Center for Clinical Bioethics at Georgetown. I am a lawyer but not for Georgetown. I am just there. Now professor Thorpe you have paid a lot of attention to what’s going on in the states and the legislatures and the new legislation. Do you see any movement either in the legislatures or in the trial courts in the direction of providing patient and research subject actual remedies for unwanted disclosures.

Jane Hyatt Thorpe: That’s a very good question and I think at this point a lot of the activity we’re seeing is just identifying breeches and identifying harm that have come from those breeches. But I think one of the challenges with this I think gets to the discussion of stigma as what is an appropriate remedy for these situations where information is disclosed, how do we quantify or define harm and then how do we remedy those harm or harms that occurred because of release of that information. And I think so far remedies have been financial in nature but I’m not sure that a financial remedy is actually a suitable remedy for some of the violations and breeches that we’ve actually seen occurring. And so I do think more thought needs to be given to that and I think there are opportunities particularly at the state level as states are rethinking their own privacy frameworks, what are the damages, what are the remedies when there are breeches, when information is lost, when information is disclosed improperly and takes on even more meaning too when you’re talking about not just individual patient because a lot of issues at this point still have been, you know small groups, larger numbers but still small groups of individuals when you have sort of a more wide scale disclosure of information that may affect a population with particular characteristics and sort of what is the remedy for that group. Thinking beyond sort of financial remedies but sort of more remedies that would either release the stigma or otherwise eliminate the damages that were done.

Joe V Selby: Okay. Well I want to thank all of you for sticking around to the end and let’s give our panelists a hand.

CONCLUDING REMARKS

Jeffrey Lerner: Okay. I'm going to make this an extremely brief conclusion because I think in a sense you voted with your feet or your seats, you've stayed and so clearly you've got quite a bit out of this. You know some of the things were in a sense anticipatable. You know you could have imagined with a conference like this we would talk about different definitions of health and illness and so on. And then there were objectives that we wanted you to think about like the interface between individual health and population health but I think there are also a third type of issue and for each of us that'll be individual. The sort of deep structure issues that may have been raised. One of them for me is basically a rethinking of what is our infrastructure in healthcare. How is it changing in terms of the balance between public and private infrastructure as big data becomes a regular part of our health care system. Now it would take longer for me to explain what I just said and I'm not going to do that. But you have I think your own issues and all I would do is come back and encourage you to keep the dialogue going. We will post the proceedings of this conference. The filming of it on our website. There are the resources on the website. You're welcome to contribute to that. You should also consider if you're a writer submitting to *Health Affairs* or the *Journal of Ambulatory Care Management* which have invited your submissions. And my final word to you is again this was a public service. You were part of that. So thank you very much. Thank you to the speakers. Thank you to the organizers. I think you really did perform a public service. I appreciate it.